Worker Protection Standard: Response to Comment Document

I. Introduction

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The purpose of this document is to summarize and respond to the comments received on the revisions to 40 CFR Part 170, the Worker Protection Standard.

The revisions were proposed on March 19, 2014 (79 FR 15444). EPA received substantial feedback on the proposal, including about 2,400 written comments with over 393,000 signatures. Commenters included state pesticide regulatory agencies, state departments of health, farmworker advocacy organizations, public health agencies, growers and grower organizations, agricultural producer organizations, applicators and applicator organizations, pesticide manufacturers and their organizations, personal protective equipment manufacturers, farm bureaus, crop consultants and organizations, the Small Business Administration (SBA) Office of Advocacy, concerned citizens, and others.

This document generally follows the same structure as the preamble for the final rule to make it easy to cross reference between the two documents. The preamble to the final rule includes a summary of the major comments and EPA's responses to them.

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II. General Support

99 A. Comments

Many commenters expressed general support for EPA's proposed revisions to the WPS and noted that the revised rule should help to prevent adverse health effects resulting from exposure to pesticides among agricultural workers and pesticide handlers. While most commenters supported the proposed changes generally, many provided comments about specific elements of the proposal that should be strengthened. Many commenters who expressed general support also raised concerns about specific elements of the proposed regulation.

B. EPA Response

EPA appreciates the commenters' general support for the proposed revisions. EPA acknowledges commenters' specific concerns and suggestions in the specific units of this response to comments document.

III. General Opposition

A. Comments

Many commenters opposed EPA finalizing the proposed changes. Some commenters suggested that EPA engage in a thorough evaluation of the existing WPS, considering the changes in agricultural practices and technology since the existing WPS was promulgated over 20 years ago. In addition, some commenters asserted that acute incidents have declined significantly since the existing WPS was implemented, demonstrating improvements in worker safety.

Another commenter suggested that EPA engage in a thorough review and dialogue related the existing WPS with state regulatory agencies and the regulated community to enhance the effectiveness of the current WPS and to develop alternative proposals. This commenter also requested that any changes to the WPS provide state regulatory agencies flexibility in structuring and enforcing certain WPS provisions to better reflect the diversity of agricultural operations in their states.

A few commenters expressed concern that EPA used outdated data on the demographics of farmworkers when more current data are available. A commenter noted that EPA relied on information from the Department of Labor's (DOL) National Agricultural Worker Survey (NAWS) from 2005, although a more recent data set is available to the public.

Several commenters argued that EPA's characterization of the existing WPS and need for the proposed changes implies that EPA has been ineffective at regulating pesticides. Commenters also asserted that the proposed rule indicates a belief on EPA's part that pesticide labels are inadequate. Commenters

- alleged that the label provides necessary protections and that by revising the WPS EPA is ignoring the
- protections inherent in the labeling. Lastly, commenters argued that the proposal overlooks the
- extensive worker protection stewardship programs of states, registrants, professional applicators,
- producers, and the regulated community.
- 133 B. EPA Response

EPA disagrees with the commenters' request not to promulgate revisions to the WPS. EPA already engaged stakeholders extensively, in both formal and informal consultations, to evaluate the existing WPS. EPA engaged in a National Assessment of the Pesticide Worker Safety Program, convened a workgroup of the Pesticide Program Dialogue Committee, convened a Small Business Advocacy Review (SBAR) Panel, and participated in many meeting with stakeholders to discuss the existing rule and to accept suggestions for improvements. Stakeholders consulted included grower organizations, farmworker organizations, cooperative extension services, commodity organizations, healthcare providers, state regulatory agencies, federal agencies, pesticide manufacturers and distributers, and individual workers, handlers, and growers. In addition, EPA encouraged comments from all stakeholders on the proposed changes to the WPS, and considered those comments in developing a final rule.

EPA discussed the changes over time in the regulation of pesticides in both the proposed and final regulations. EPA acknowledges that agriculture has changed over time and technology has advanced. However, the WPS is focused on protecting workers and handlers from pesticide exposure through a generally applicable regulation that applies regardless of the agricultural practices or technology used. Changes in agricultural practices and technology, such as using pesticides with a lower application rate or shorter REI, applying pesticides using drift reduction technology, or mixing and loading using a closed system, are additional ways to reduce potential exposure to workers and handlers. However, these measures do not replace or negate the need for the protections provided under the WPS.

EPA notes that some data show that incidents of occupational pesticide exposure in agriculture have declined over time. Many factors may have contributed to this reduction, including implementation of the WPS, registration of lower risk pesticides, and adoption of safer application technology. However, avoidable and preventable incidents continue to affect workers and handlers; EPA intends to further reduce the number and severity of incidents occurring through updating the protections in the WPS.

EPA disagrees with commenters' suggestion to engage in additional review and dialogue with state regulatory agencies and the regulated community instead of finalizing the revised WPS, because EPA already conducted a significant National Assessment of the Pesticide Worker Safety Program to evaluate implementation of the existing WPS and to request suggestions for improving its effectiveness. The National Assessment of the Pesticide Worker Safety Program resulted in a variety of suggestions to improve the existing WPS, which came from the many stakeholders who participated in the process. EPA took actions following the assessment process to improve implementation of the existing WPS by:

- Revising and developing improved outreach and compliance assistance materials (including a revised How to Comply with the WPS manual released in 2005)
- Improving guidance and expanding training for enforcement inspectors, and increasing oversight by EPA regional offices
- Improving training materials for train-the-trainer programs
- Expanding funding of pesticide incident monitoring
- Revising grant guidance to states for improved enforcement tracking, incident monitoring and program reporting

While EPA was able to take some actions to improve the existing WPS immediately following the National Assessment process, other recommendations require regulatory change to implement. For example, expanding the content of worker and handler pesticide safety training and requiring respirator fit testing consistent with OSHA and National Institute for Occupational Safety and Health (NIOSH)

requirements require EPA to revise the requirements of the existing WPS. Given the many opportunities for stakeholders to engage with EPA prior to publication of the proposed rule and to provide comments during the public comment period, EPA rejects commenters' request for further review and dialogue between EPA, state regulatory agencies, and the regulated community prior to publishing a final rule.

EPA notes that nationally consistent implementation of the WPS is a necessary underpinning of the pesticide regulatory decisions made by EPA. EPA will work with state regulatory agencies on enforcing the WPS. Additionally, EPA has incorporated an equivalency provision in the final rule to allow states to request EPA to review portions of their laws protecting workers and handlers to determine if they are equivalent to the protections offered under the WPS.

EPA agrees with commenters that the farmworker demographic data used in the preamble to the proposed rule was from 2005, and notes that the preamble to the final rule uses the most current data available from NAWS.

EPA disagrees with commenters' assertions that the proposed changes to the WPS imply that EPA has been ineffective at regulating pesticides. EPA believes that the current system for regulating pesticide products is generally adequate, and that pesticides can be used safely and effectively when the labeling is followed. EPA relies on the complementary relationship between the labeling and the WPS, which is referenced as part of labeling, to protect workers and handlers. EPA's proposal to improve the WPS protections does not mean that EPA believes pesticide registration and labeling are not effective. Rather, EPA's registration decisions and labeling language requirements are predicated on the premise that employers, workers and handlers are complying with the important workplace protections, training, and hygiene measures specified in the WPS. If the existing WPS does not ensure that the assumed protections are occurring, e.g., workers are entering treated areas before the REI expires or experiencing pesticide exposure through drift from products applied according to labeling requirements, then EPA must review the existing regulation to address these shortcomings and to ensure that the basis on which the labeling decisions rest is sound.

EPA disagrees with comments that labeling alone provides sufficient protection to workers and handlers. Under FIFRA's authority, EPA has implemented measures to protect workers, handlers, other persons, and the environment from pesticide exposure in two primary ways. First, EPA includes product-specific use instructions and restrictions on individual pesticide product labeling. These instructions and restrictions are the result of EPA's stringent registration and reevaluation processes and are based on the risks of the particular product. Since users must comply with directions for use and restrictions on a product's labeling, EPA uses the labeling to convey mandatory requirements for how the pesticide must be used to protect people and the environment from unreasonable adverse effects of pesticide exposure. Second, EPA enacted the WPS to expand protections against the risks of agricultural pesticides without making individual product labeling longer and much more complex. The WPS is a uniform set of requirements for workers, handlers and their employers that are generally applicable to all agricultural pesticides and are incorporated onto agricultural pesticide labels by reference. Its requirements complement the product-specific labeling restrictions and are intended to minimize occupational exposures generally.

EPA has included in the preamble to the final rule a discussion of EPA's regulation of pesticides, including a summary of the data required and the process for evaluating the data to determine whether to register a product and what, if any, labeling-based risk mitigation measures are necessary. The final rule preamble also includes a discussion of the complementary relationship between pesticide labeling and the WPS.

EPA recognizes that a number of stewardship activities may support worker and handler safety. However, because pesticide registration and labeling decisions depend on assurance that specific protections are being provided to workers and handlers, it is not possible to rely on voluntary stewardship programs alone. To ensure that workers and handlers receive the protections assumed when EPA reviews data and establishes risk mitigation measures during the pesticide registration and registration review processes, EPA must establish enforceable requirements under the WPS.

IV. Context and Goals of This Rulemaking

A. Context for this Rulemaking

1. Statutory authority. Enacted in 1947, FIFRA established a framework for the pre-market registration and regulation of pesticide products; since 1972, FIFRA has prohibited the registration of pesticide products that cause unreasonable adverse effects. FIFRA makes it unlawful to use a pesticide in a manner inconsistent with the labeling and gives EPA's Administrator authority to develop regulations to carry out the Act. FIFRA's legislative history indicates that Congress specifically intended for FIFRA to protect workers and other persons from occupational exposure directly to pesticides or to their residues (Ref. 5).

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2. EPA's regulation of pesticides. EPA uses a science-based approach to register and re-evaluate pesticides, in order to protect human health and the environment from unreasonable adverse effects that might be caused by pesticides. The registration process begins when a manufacturer submits an application to register a pesticide. The application must contain required test data, including information on the pesticide's chemistry, environmental fate, toxicity to humans and wildlife, and potential for human exposure. EPA also requires a copy of the proposed labeling, including directions for use and appropriate warnings.

Once an application for a new pesticide product is received, EPA conducts an evaluation, which includes a detailed review of scientific data to determine the potential impact on human health and the environment. EPA considers the risk assessments and results of any peer review, and evaluates potential risk management measures that could mitigate risks that exceed EPA's level of concern. In the registration process, EPA evaluates the proposed use(s) of the pesticide to determine whether it would cause adverse effects on human health, non-target species, and the environment. In evaluating the impact of a pesticide on occupational health and safety, EPA considers the risks associated with use of the pesticide (occupational, environmental) and the benefits associated with use of the pesticide (economic, public health, environmental). However, FIFRA does not require EPA to balance the risks and

benefits for each audience. For example, a product may pose risks to workers, but risk may nevertheless be reasonable in comparison to the economic benefit of continued use of the product to society at large.

If the application for registration does not contain evidence sufficient for EPA to determine that the pesticide meets the FIFRA registration criteria, EPA communicates to the applicant the need for more or better refined data, labeling modifications, or additional use restrictions. Once the applicant has demonstrated that a proposed product meets the FIFRA registration criteria and any applicable requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 321 et seq., EPA approves the registration subject to any risk mitigation measures necessary to meet the FIFRA registration criteria. EPA devotes significant resources to the regulation of pesticides to ensure that each pesticide product meets the FIFRA requirement that pesticides not cause unreasonable adverse effects to the public and the environment.

When EPA approves a pesticide, the labeling generally reflects all risk mitigation measures required by EPA. The risk mitigation measures may include requiring certain engineering controls, such as the use of closed systems for mixing pesticides and loading them into application equipment to reduce potential exposure to those who handle pesticides; establishing conditions on the use of the pesticide by specifying certain use sites, maximum application rate or maximum number of applications; or establishing REIs during which entry into an area treated with the pesticide is generally prohibited until residue levels have declined to levels unlikely to cause unreasonable adverse effects. Because users must comply with the directions for use and use restrictions on a product's labeling, EPA uses the labeling to establish and convey mandatory requirements for how the pesticide must be used to protect the applicator, the public, and the environment from pesticide exposure.

Under FIFRA, EPA is required to review periodically the registration of pesticides currently registered in the United States. The 1988 FIFRA amendments required EPA to establish a pesticide reregistration program. Reregistration was a one-time comprehensive review of the human health and environmental effects of pesticides first registered before November 1, 1984 to make decisions about these pesticides' future use. The 1996 amendments to FIFRA require that EPA establish, through rule making, an ongoing "registration review" process of all pesticides at least every 15 years. The final rule establishing the registration review program was signed in August 2006 (Ref. 16). The purpose of both re-evaluation programs is to review all pesticides registered in the United States to ensure that they continue to meet current safety standards based on up-to-date scientific approaches and relevant data.

Pesticides reviewed under the reregistration program that met current scientific and safety standards were declared "eligible" for reregistration. The results of EPA's reviews are summarized in Reregistration Eligibility Decision (RED) documents. The last RED was completed in 2008. Often before a pesticide could be determined "eligible," additional risk reduction measures had to be put in place. For a number of pesticides, measures intended to reduce exposure to handlers and workers were needed and are reflected on pesticide labeling. To address occupational risk concerns, REDs include mitigation measures such as: Voluntary cancellation of the product or specific use(s); limiting the amount, frequency or timing of applications; imposing other application restrictions; classifying a product or specific use(s) for restricted use only by certified applicators; requiring the use of specific PPE; establishing specific REIs; and improving use directions. During this process, EPA also encouraged registrants to find replacements for the inert ingredients of greatest concern. As a result of EPA's reregistration efforts, current U.S. farm workers are not exposed to many of the previously used inert ingredients that were of the greatest toxicological concern.

EPA's registration review program is a recurring assessment of products against current

standards. EPA will review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration. Pesticides registered before 1984 were reevaluated initially under the reregistration program. These and pesticides initially registered in 1984 or later are all subject to registration review.

In summary, EPA's pesticide reregistration and registration reviews assess the specific risks associated with particular chemicals and ensure that the public and environment do not suffer unreasonable adverse effects from those risks. EPA implements the risk reduction and mitigation measures identified in the pesticide reregistration and registration review programs through amendments to individual pesticide product labeling.

3. WPS. The WPS regulation is incorporated by reference on certain pesticide product labeling through a statement in the agricultural use box. The WPS provides a comprehensive collection of pesticide management practices generally applicable to all agricultural pesticide use scenarios in crop production, complementing the product-specific requirements that appear on individual pesticide product labels.

The risk reduction measures of the WPS may be characterized as being one of three types: Information, protection and mitigation. To ensure that employees will be informed about exposure to pesticides, the WPS requires that workers and handlers receive training on general pesticide safety, and that employers provide access to information about the pesticides with which workers and handlers may have contact. To protect workers and handlers from pesticide exposure, the WPS prohibits the application of pesticides in a manner that exposes workers or other persons, generally prohibits workers and other persons from being in areas being treated with pesticides, and generally prohibits workers from entering a treated area while an REI is in effect (with limited exceptions that require additional protections). In addition, the rule protects workers by requiring employers to notify them about areas on the establishment treated with pesticides, through posted and/or oral warnings. The rule protects handlers by ensuring that they understand proper use of and have access to required PPE. Finally, the WPS has provisions to mitigate exposures if they do occur by requiring the employer to provide to workers and handlers with an ample supply of water, soap and towels for routine washing and emergency decontamination. The employer must also make transportation available to a medical care facility if a worker or handler may have been poisoned or injured by a pesticide and provide information about the pesticide(s) to which the person may have been exposed.

EPA manages the risks and benefits of each pesticide product primarily through the labeling requirements specific to each pesticide product. If pesticide products are used according to the labeling, EPA does not expect use to cause unreasonable adverse effects. However, data on incidents of adverse effects to human health and the environment from the use of agricultural pesticides show that users do not always comply with labeling requirements. Rigorous ongoing training, compliance assistance and enforcement are needed to ensure that risk mitigation measures are appropriately implemented in the field. The framework provided by the WPS is critical for ensuring that the improvements brought about by reregistration and registration review are realized in the field. For example, the requirement for handlers to receive instruction on how to use the pesticide and the application equipment for each application is one way to educate handlers about updated requirements on product labeling to ensure they use pesticides in a manner that will not harm themselves, workers, the public or the environment. In addition, the REIs are established through individual product labeling, but action needs to be taken at the use site to ensure that workers are aware of areas on the establishment where REIs are in effect and given directions to be kept out of the treated area while the REI is in effect. The changes to the WPS are designed to enhance the effectiveness of the existing structure of protections and to better realize

labeling-based risk mitigation measures at the field level.

B. Goals of This Rulemaking

Discussions with stakeholders over many years, together with EPA's review of incident data, led EPA to identify several shortcomings in the current regulation that will be addressed by this final rule. As discussed in Unit IV.A., EPA uses both product-specific labeling and the WPS to effectuate occupational protections for workers and handlers. EPA engages in ongoing reviews and reassessments of pesticide products to ensure they continue to meet the standard of not causing unreasonable adverse effects to human health and the environment. The WPS must be updated to ensure that the rule continues to complement the labeling-based protections and to address issues identified through experience with the WPS, and review of incident data and stakeholder engagement.

1. Purpose of the WPS. The WPS is intended to reduce the risks associated with occupational pesticide exposure to workers, handlers and their families, and to protect others and the environment from risks of pesticide use in agricultural production. The rule makes employers of workers and handlers responsible for providing protections to workers and handlers on their establishments. By imposing this obligation, EPA seeks to ensure those who make pesticide use decisions (employers) internalize the effects of their decision making rather than passing on the costs associated with these decisions (risks of pesticide exposure) to others (workers and handlers).

As noted in Unit IV.A., the components of the WPS generally can be grouped into three categories: Information, protection, and mitigation. Employers must provide workers and handlers with information needed to protect themselves, others, and the environment from pesticides and pesticide residues through pesticide safety training, pesticide application and hazard information, and access to labeling. Employers must provide protections to workers and handlers during and after applications in order to minimize potential for exposure. Finally, employers must be prepared to mitigate exposures that do occur by providing supplies for washing and emergency decontamination, and emergency transportation to a medical facility if necessary. These elements are necessary to implement productspecific labeling requirements effectively. For example, pesticide safety training informs workers that areas treated with pesticides are off limits for entry for a certain period after the application, i.e., a product-specific REI, and that their employers will inform them of where and when REIs are in effect and entry into the treated areas is prohibited. In some instances, employers must provide further protection by posting warning signs at treated areas while REIs are in effect to remind workers to keep out of the treated areas. For handlers, training informs them about basic pesticide safety and handling precautions and reducing the potential to expose themselves or others. In addition, the employer must provide information for each application, informing the handler about the product-specific labeling restrictions and requirements.

In summary, the WPS works in conjunction with product labeling to protect workers and handlers from occupational pesticide exposure. The rule imposes on the employer the responsibility for providing protections to workers and handlers and to ensure they have access to information necessary to protect themselves and others during and after pesticide application.

2. Surveillance data. When EPA promulgated the existing rule, it used existing data on occupational pesticide-related incidents to estimate that that approximately 10,000 to 20,000 incidents of physician-diagnosed (not hospitalized) pesticide poisonings occurred in the WPS-covered workforce annually. For this rulemaking, EPA estimates that about 1,810 to 2,950 acute pesticide exposure incidents occur annually on agricultural establishments that potentially could be prevented by the WPS. This substantial drop in the estimated number of incidents shows that the existing rule and efforts by employers, workers and handlers have made great accomplishments in reducing pesticide exposure for

workers and handlers. Pesticide use in agriculture is safer than it was 20 years ago.

Current occupational health incident surveillance data show, however, that avoidable incidents continue to occur. For example, some of the occupational pesticide illnesses reported to state health agencies have occurred when workers entered a treated area before the REI expired. Although employers are obligated to warn workers to keep out of treated areas and to ensure that workers receive training on and information about treated areas, incidents continue to occur. Another example of potentially avoidable exposure is spray drift. Labeling instructs handlers to apply pesticides in a manner that does not contact other persons, but pesticide drift continues to cause exposure incidents. In addition to surveillance data, studies also show that pesticide residues are brought home by workers and handlers on their bodies and clothing (known as "take-home exposure"), creating an exposure pathway for family members.

This rulemaking is intended to reduce avoidable incidents by improving information, protections, and mitigations for workers and handlers without imposing unreasonable burdens on employers. Although EPA cannot quantify the specific reduction in incidents from any single change to the regulation, taken together, EPA estimates that the final rule will result in an annual reduction of between 540 and 1,620 acute, health-related incidents. In addition, EPA expects that the final rule will help reduce chronic health problems among workers and handlers by reducing daily pesticide exposures, and thereby improving quality of life throughout their lives, resulting in a lower cost of health care and a healthier society. (See Unit II.C.) Units V. through XIX. describe the final regulatory requirements and their potential to reduce avoidable incidents. The Economic Analysis for this rulemaking provides an estimate of the costs of the requirements and a quantitative and qualitative discussion of the potential benefits, including avoiding acute pesticide-related illnesses in workers and handlers (Ref. 1).

3. Demographics of workers and handlers. In addition to the complexity of the science issues involving pesticide use, variability of pesticide use patterns and incomplete information about occupational pesticide-related illnesses and injuries, the diversity of the labor population at risk and the tasks they perform makes it challenging to ensure that workers and handlers are adequately protected.

According to the most recent public data set available from the DOL's NAWS for 2011-2012, 64% of agricultural workers in the United States were born in Mexico and 6% in Central and South America (Ref. 6). A majority (69%) of all survey respondents speak Spanish as their primary language (Ref. 6). Approximately 65% of this population speaks a little or no English; 38% cannot read English at all and another 30% can only read English "a little" (Ref. 6). Many have received only some formal education; on average, the highest grade completed by foreign-born workers was seventh grade (Ref. 6).

Approximately 17% of the survey respondents were classified as migrant, having traveled at least 75 miles in the previous year to find a job in agriculture (Ref. 6). Only 17% of respondents lived in housing provided by their employer and 55% rented housing from someone other than their employer (Ref. 6). In general, agricultural workers surveyed by NAWS do not have access to employer-provided health insurance – in 2011-2012, only 21% of farmworkers reported having the option for employer-provided health insurance (Ref. 6). USDA research, based on NAWS data, also reports that workers have difficulty entering the health care system to receive treatment (Ref. 7). Cost was a significant barrier for two-thirds of farmworkers, while about a third listed language barriers as an impediment to receiving care. Most workers fear that seeking treatment will result in losing their job because someone will replace them while they are getting treatment or the employer will label them as troublemakers and dismiss them. The problem is more severe among undocumented workers because they fear seeking treatment will lead to deportation or other adverse legal action (Ref. 7). A USDA report indicates that

the factors mentioned previously contribute to the disadvantaged status of hired workers in agriculture (Ref. 7).

The NAWS found that 19% of workers and handlers surveyed earned less than \$10,000 annually from agricultural work, and another 39% earn between \$10,000 and \$20,000 annually. Over 55% of respondents reported a total family income below \$22,500 (Ref. 6).

Both the existing WPS and the changes included in the final rule seek to eliminate some of the potential barriers to achieving effective protection of these persons by requiring training in a manner that workers and handlers can understand, requiring the employer to ensure that handlers understand relevant portions of the labeling before handling a pesticide, and expanding training to provide information on seeking medical care in the event of a pesticide exposure and highlighting the anti-retaliation provisions of the WPS.

- 4. Summary of the final rule. The final rule amends the WPS by:
- Requiring pesticide safety training at one-year intervals and amending the existing pesticide safety training content.
- Requiring recordkeeping for pesticide safety training.

- Eliminating the "grace period" that allowed workers to enter a treated area to perform WPS tasks before receiving full pesticide safety training.
- Establishing a minimum age of 18 for handlers and early-entry workers.
- Establishing requirements for specific training and notification for workers who enter an area under an REI.
- Restricting persons' entry into certain areas surrounding application equipment during an application.
- Clarifying requirements for supplies for routine washing and emergency decontamination.
- Requiring employers to post warning signs around treated areas when the product applied
 has an REI greater than 48 hours and allowing the employer to choose to post the treated
 area or give oral notification when the product applied has an REI of 48 hours or less (unless
 the labeling requires both types of notification).
- Requiring employers to maintain and make available copies of the SDSs for products used on the establishment.
- Requiring employers to provide application information and SDSs to designated representatives making the request on behalf of workers or handlers.
- Adding elements to the requirement to maintain application-specific information.
- Adopting by cross reference certain OSHA requirements for employers to provide training, fit testing and medical evaluations to handlers using products that require use of respirators.
- Requiring employers to provide supplies for emergency eye flush at all pesticide mixing and loading sites when handlers use products that require eye protection.
- Maintaining the immediate family exemption and ensuring it includes an exemption from the new minimum age requirements for handlers and early-entry workers.
- Expanding the definition of "immediate family" to allow more family-owned operations to qualify for the exemptions to the WPS requirements.
- Revising definitions to improve clarity and to refine terms.

Restructuring the regulation to make it easier to read and understand.

Units V. through XVIII. discuss the final rule requirements and elements considered in the proposal but not included in the final rule. Unit XIX. discusses implementation of the final regulatory requirements. Each of these Units generally describes the existing rule, proposal and final regulatory requirements (where appropriate), and summarizes the major comments received and EPA's responses.

EPA has grouped the discussion of the final rule and elements considered in the proposal but not included in the final rule as follows:

- Unit V: Pesticide Safety Training for Workers and Handlers.
- Unit VI: Notification.

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- Unit VII: Hazard Communication.
- Unit VIII: Information Exchange Between Handler and Agricultural Employers.
- Unit IX: Drift-Related Requirements.
 - Unit X: Establish Minimum Age for Handling Pesticides and Working in a Treated Area while an REI is in Effect.
 - Unit XI: Restrictions on Worker Entry into Treated Areas.
 - Unit XII: Display of Pesticide Safety Information.
 - Unit XIII: Decontamination.
 - Unit XIV: Emergency Assistance.
 - Unit XV: Personal Protective Equipment.
 - Unit XVI: Decision not to Require Monitoring of Handler Exposure to Cholinesterase-Inhibiting Pesticides.
 - Unit XVII: Exemptions and Exceptions.
- Unit XVIII: General Revisions.
- Unit XIX: Implementation.

V. Pesticide Safety Training for Workers and Handlers

- A. Shorten Retraining Interval for Workers and Handlers
- 1. Current rule and proposal. The existing WPS requires employers to ensure that workers and handlers are trained once every five years. EPA proposed to establish an annual retraining interval for workers and handlers in order to improve the ability of workers and handlers to protect themselves and their families from pesticide exposure.
- 2. Final rule. In the final rule, EPA has adopted the proposed requirement for workers and handlers to receive full pesticide safety training annually. The final regulatory text for these requirements is available at 40 CFR 170.401(a) and 170.501(a).
 - 3. Comments and responses.

Comments.

Several farmworker advocacy groups, public health organizations and academics, public health agencies, and PPE manufacturers supported full, annual training, stating that the more frequent training would improve workers' and handlers' ability to protect themselves and their families, and that annual training would be simple to track administratively. Many of these commenters stated that annual safety training would be comparable to training required by OSHA in other industries.

Agricultural producer organizations, growers, pesticide producers, the SBA Office of Advocacy, farm bureaus, and state pesticide regulatory agencies expressed concern for the burden annual training

would place on agricultural employers. Some stated that farmworkers would be insulted by the repeated trainings, and asked for evidence that increased training would lead to reduced pesticide exposure. Some of these entities, including the SBA Office of Advocacy, recommended an initial indepth training for new workers followed annually by a shortened "refresher" training. A similar suggestion was to require initial in-depth training for workers and handlers, followed by four years of refresher training, with an in-depth training every fifth year. Some states suggested training every two or three years, or allowing each state to set its own training interval, to parallel the state's pesticide applicator recertification interval. A few states recommended a system where the training timeframe is based on the calendar year, to allow flexibility for employers. For example, under this proposal, an employee trained in March 2014 could be retrained as late as December 2015. This suggestion would extend the permitted interval between worker and handler trainings to as long as two years. Comments from pesticide industry organizations suggested that the frequency of worker safety training be commensurate with an individual workers' tasks, previous training, and experience.

One commenter provided a specific alternative. The SBA Office of Advocacy reiterated the comments of the SBAR Panel, convened in 2008. The SBAR Panel report recognized the importance of training workers and handlers to remind them of the safety principles, but recommended that EPA consider flexibilities for small establishments. Specifically, the SBAR Panel suggested that EPA consider a reduced training frequency where all of the following conditions are met: (1) no new workers are hired during the interval; (2) no new or different pesticide applications are made as compared to the previous year, and (3) the workers and handlers were trained on the establishment previously. Small establishments requesting this flexibility would need to document their compliance with these conditions. The comment from SBA stated that EPA almost always follows the Panel consensus recommendation, and highlights that EPA should discuss the recommendations and final position.

The SBA Office of Advocacy also commented that the proposal for retraining would have required a higher standard for trainers, and would require employers to provide all workers a copy of the training record, adding burden to employers. SBA Office of Advocacy noted that most small businesses retrain annually due to high worker turnover, despite the five year maximum retraining interval in the current rule, and retain records of the training.

<u>EPA Response</u>. EPA considered the alternatives described for training frequency, and agrees with the comments that annual training, in some form, is the appropriate interval to ensure that workers and handlers receive more frequent reinforcement of the safety principles. EPA rejected the suggestion for a limited refresher training based on the difficulty both employers and regulators would face in tracking multiple levels of training among a mobile workforce, the burdens of maintaining multiple forms of training materials and providing different trainings where employees are on differing cycles for full and refresher training, and the fact that very little of the substantive content of the required training appears to be material that would not need to be brought to employees' attention annually.

The suggestions for biennial or triennial training and allowing the states to base the frequency of training for workers and handlers on their pesticide applicator recertification requirements would present similar administrative problems with tracking trainings and introduce the possibility that workers or handlers would miss information needed to protect themselves. Finally, the alternative to establish the frequency of training based on the calendar year presents similar issues with tracking training and needed frequency of repetition.

The recommendation for training to be tailored to the individual workers' tasks, experience, and prior training was rejected based on the difficulty in tracking the specific training needs with a mobile

workforce, the need for multiple forms of training materials, and the potential burden on employers to determine specific needs for each employee. In addition, the training gives practical information that is useful to everyone who works with or around agricultural pesticides.

Comments that farmworkers would resent the more frequent training do not comport with the information available to the EPA. In response to the proposal, EPA received comments from farmworkers related to training frequency. In one survey provided by Cabrillo, 78% of the farmworkers asked how often they should receive training responded that annual training should be provided. Letters from Spanish-speaking farmworkers submitted to the docket included similar requests for annual training.

Commenters that asked for evidence that increased frequency of training would lead to reduced pesticide exposure should refer to the discussion of evidence supporting annual training in the preamble for the proposed rule. (Ref. 2, Unit VII.A.)

The revisions to the WPS will not cause a significant impact on a substantial number of small entities. EPA has already certified that there is not a significant impact on a substantial number of small entities which would trigger the requirement for an SBAR Panel review. However, EPA opted to conduct a SBAR Panel review to gather more information related to the impact of the proposed regulations, and included discussion of the retraining interval for workers. The recommendation from the SBAR Panel regarding the retraining interval encouraged EPA to consider flexibility for less frequent training for small entities. EPA agrees that the SBAR Panel recommendation could reduce burden on small entities, but it would also reduce the benefit workers would receive from annual training. EPA considered the recommendation for reduced training, but notes that the SBAR Panel alternative would increase recordkeeping burdens for all small establishments that would – to some degree – offset their savings from fewer trainings. The additional burden to document compliance with the SBAR Panel alternative's requirements would include recordkeeping documenting that: (1) no new workers are hired during the reduced training interval; (2) no new or different pesticide applications are made during the reduced training interval, and (3) the specific workers were trained on the establishment within the reduced training interval. Those costs were not estimated, but EPA expects that they would be higher than those estimated for the proposed recordkeeping for all workers. Based on the marginal cost reduction and potential risk to workers who would not receive training annually, EPA believes that annual training is more protective. And in any case, the revisions to the WPS will not cause a significant impact on a substantial number of small entities.

EPA has responded to comments from SBA Office of Advocacy and others about the burden on employers from eliminating the option for certified applicators to train workers and on the proposed requirement for employers to provide all workers and handlers with a copy of the training by reinstating certified applicators as trainers of workers and limiting the requirement for providing training records to only requesting employees. SBA Office of Advocacy noted that most small businesses retrain annually due to high worker turnover, despite the five year maximum retraining interval in the current rule, and retain records of the training.

B. Establish Recordkeeping Requirements to Verify Training for Workers and Handlers

1. Current rule and proposal. The existing WPS does not specify how an employer must verify that a worker or handler has received pesticide safety training. EPA proposed to eliminate the existing voluntary training verification card system and to require employers to maintain records of WPS worker and handler training for two years. EPA proposed that the training record include, among other things, the employee's birthdate to verify minimum age for early-entry worker or handler activities. EPA proposed to require the employer to provide a copy of the record to each worker or handler upon

completion of the training.

2. Final rule. EPA has finalized the proposed requirement for employers to maintain records of worker and handler training for two years. Required information for the record of worker and handler training includes the trained worker's or handler's name and signature, the date of training, the trainer's name, evidence of the trainer's qualification to train, the employer's name, and which EPA-approved training materials were used. EPA has not included in the final rule the proposed requirement for the employer to record or retain the birthdate of the employee. The final rule does not require employers to automatically provide a copy of the training record to each worker and handler; instead, the final rule only requires the employer to provide a copy of the training record to the trained employee upon the employee's request. The final regulatory text for the worker and handler training recordkeeping requirements appears at 40 CFR 170.401(d) and 170.501(d), respectively.

3. Comments and responses.

<u>Comments that recordkeeping does not improve worker safety</u>. Several farm bureaus, pesticide manufacturers, and some state pesticide regulatory agencies commented that the requirement for the employer to make and keep training records is for determining compliance but does not improve worker safety.

A pesticide industry organization stated that there is a body of research supporting the notion that better training and good supervision protect better than creating records.

<u>EPA Response.</u> EPA agrees with the comments that state that recordkeeping, in itself, does not improve worker safety. However, the requirement for employers to retain documentation that training has been provided is expected to improve compliance with the rule. One state agency indicated that unless employers are held accountable, they may not take the requirement seriously. Even for those employers with the strongest commitment to worker training, training records can be a useful tool to track employee trainings and make sure their employees receive the protections provided through training and are able to protect themselves. The training recordkeeping will also be used to provide verification to future employers to demonstrate that a worker or handler has been properly trained.

Statements that the states will need to verify training are correct. FIFRA section 26 gives states primary enforcement responsibility in regard to pesticide use violations, which include the requirements of the WPS. Currently, in the absence of training records, inspectors generally rely on interviews with workers and handlers to determine whether training has been provided, and have stated that it is difficult to determine whether training has been provided. Workers may not consistently recall when or whether they were provided training or may not be able to communicate clearly with an inspector due to language differences. Please refer to the preamble of the proposed rule (Ref. 2, Unit VII.B.3.) for a discussion of these issues. Reliance on both records and interviews will provide a more reliable assessment of whether workers have been properly trained.

EPA does not agree that the recordkeeping of training is highly burdensome to employers. One farm bureau commenter found the proposed recordkeeping manageable. EPA is convinced that the benefits of training and training recordkeeping exceed the burden on employers, who benefit economically from worker and handler activity.

<u>Comments – support for recordkeeping.</u> Comments from state regulatory agencies, farmworker advocacy organizations, a grower organization, and academics in support of a requirement for recordkeeping stated that it would ensure employees received the training and that it would improve enforcement and compliance. One applicator organization and two state regulatory agencies support the recordkeeping to demonstrate that a person was trained.

One farm bureau finds the burden for growers to be manageable. One grower stated that they

have maintained records of training for many years.

Another state regulatory agency supports employer recordkeeping of worker training, from the date of employment until one year after they are either separated or retrained, and two farmworker advocacy organizations support the training recordkeeping and distribution to employees.

One grower/public citizen had this to say:

"I track a person's training and retraining by using a roster spreadsheet that they [workers] sign...I feel the responsibility of retaining a training roster is the responsibility of the individual employer/employee."

<u>EPA Response.</u> EPA agrees with the commenters that recordkeeping is necessary for the purpose of compliance monitoring and to ensure that workers and handlers receive the required training.

Comments in opposition to recordkeeping on basis of burden to the state or agricultural employers. One state regulatory agency argued that states would have to verify the training record, which would be burdensome. They noted that the state and the employer would be responsible for verifying the training. Several farm bureaus and a pesticide manufacturer, as well as some state regulatory agencies, stated that the requirement would be burdensome to employers.

One farm bureau stated that collecting the date of birth, the trainer's credentials, and the training materials used, as required under the proposal, would be "time consuming and restrictive."

<u>EPA Response</u>. EPA agrees that the state regulatory agency would need to verify training from employer records. Currently, inspectors must rely on interviews and in some instances on the training verification card to determine if a worker or handler has been trained. Using a combination of an interview and comparison with the training record can provide a more reliable assessment of whether workers and handlers have been properly trained.

EPA has revised the requirement to eliminate the documentation of the birth date. The information describing the trainer's credentials and the materials used for training need be captured only once per specific training. EPA finds that the benefit to workers and handlers from annual training and recordkeeping of training outweighs the burden on employers to collect and retain the information.

Comments in opposition to training records because benefits cannot be quantified. Several farm bureaus and pesticide manufacturers, some grower groups, and state regulatory agencies stated that, due to the burden on growers and because EPA stated that it is unable to quantify the benefits associated with the training records, the need for recordkeeping is not supported and should not be implemented.

EPA Response to benefits. EPA disagrees with the contention that, because the benefits of keeping records of training cannot be quantified, that the requirement is not supported. Recordkeeping increases incentive to comply with requirements. Increased compliance with the requirement to provide pesticide safety training to workers and handlers should result in increased safety of workers and handlers. Employers benefit from recordkeeping because inspectors would review documentation of training rather than relying on the memory of workers and handlers about when and whether they were trained. EPA directs the commenter to review Unit VII. of the preamble of the proposed rule (Ref. 2) for information that describes the benefits of training. One specific benefit, from an association that provides safety training, is that repeating safety messages increases the adoption of improved safety practices. Although these benefits, and others identified in the preamble to the proposed rule, cannot be quantified, EPA finds them compelling, and that they justify the burden on employers.

Comments in opposition to the requirement to distribute records to all workers and handlers. Several grower organizations, a public health organization, and two state regulatory agencies stated that the proposed requirement to distribute the record to every trained worker or handler would be

burdensome and that most workers or handlers would not take or keep the records. One state regulatory agency commented that state lead agencies should not have to rely on the record provided to the worker or handler to verify training, because state lead agencies may not be able to confirm with the person who issued the record that it is valid.

<u>EPA Response.</u> EPA agrees with commenters that providing a copy of the training record to each worker and handler would be unduly burdensome, and has modified the requirement. The final rule requires employers to provide training records to the trained employee only on the employee's request. This will reduce the burden on employers while ensuring that interested employees will be able to demonstrate to future employers that they were appropriately trained.

Subsequent employers would be responsible, as in the current rule, to decide whether the provided training record was valid. If the new employer believes the provided record is falsified, the new employer must provide the safety training to the employee. However, if a worker or handler presents a valid training record to an employer indicating he or she has been trained according to the rule within the last year, and the employer has no reason to believe the record has been falsified, the employer could retain a copy of the training record as proof the worker or handler has been trained. If a state confirms that a training record is invalid, the employer must provide training to the worker or handler.

Comments in support of proposal to provide training records to employees. One grower organization supported the requirement for training documentation to be given to all workers to prove to subsequent employers that they have been trained. Many commenters recommended the record be provided to the worker or handler only upon their request to reduce burden.

<u>EPA Response.</u> EPA agrees that the record can be useful to demonstrate to future employers that workers or handlers have been trained. EPA also agrees with commenters that not all workers or handlers may want or need documentation of training. EPA has revised the final rule to reflect that the training record need only be provided to workers and handlers on their request.

Comments opposed to requiring birthdate in the record. There were a number of comments from state regulatory agencies, one grower organization, and farmworker advocacy organizations related to the proposed requirement that employers include the trained employee's birthdate among the information to be recorded to document training. EPA proposed including the trained employee's birthdate in the recordkeeping in order to facilitate the employer's verification that a worker or handler met the minimum age requirement for handling pesticides or entering treated areas under an REI as allowed under the early entry exceptions. States and other commenters noted that a person's birthdate can be considered confidential and personal information, the distribution of which can lead to identity theft.

Farmworker advocacy groups also expressed concern that workers would be denied employment based on their age.

<u>EPA Response.</u> EPA has decided the advantages of requiring the employer to record the birthdate of the trained worker or handler are outweighed in this instance by concerns for protecting confidential and personal information. Under the final rule, the employer is responsible for determining that each employee has met applicable the minimum age requirement. The final rule does not include the proposed requirement for the employer to collect or retain specific documentation of the employee's birthdate or age. However, the employer must verify that early-entry workers and handlers meet the minimum age of 18 prior to performing those tasks.

In response to farmworker advocacy organization concerns regarding employers discriminating on the basis of age, the revised rule eliminates the birthdate as a required element. EPA believes that the protecting persons under 18 years of age from the pesticide exposures associated with handler

duties and early-entry worker tasks is more important than the possibility that employers' inquiries into age might lead to age-based discrimination. The Age Discrimination in Employment Act (29 U.S.C. 621 et seq.) forbids age discrimination against people who are age 40 or older, and some states have laws that protect younger workers from age discrimination. Employers may not direct a person under 18 years of age to perform handler duties or early-entry worker tasks.

Comments opposing the provided record due to concerns for falsification. One farm bureau, a state lead agency and a marketing group expressed concern for falsification of these employer-created records. One state pesticide regulatory agency stated that because many workers and handlers are undocumented, there will be falsification of the records. Another state pesticide regulatory organization stated that they do not support recordkeeping on the basis that it is likely that fraudulent records will be used, and because verification of the record will burden the state regulatory agency. One grower group asked how the proposed record, which would be given to the worker or handler, would reduce fraudulent records as compared to the verification card system, stating that the training record is not different in that it could also be compromised. This commenter asserted the main change to be the recordkeeping burden to the employer, and stated that if EPA cannot demonstrate how this is an improvement, the current system should be retained.

Another state regulatory agency asked for the specific benefits of the proposed change, and for a viable program of verification to be implemented, such as using the verification card system. Another commented that state lead agencies should not have to rely on the provided record to verify training, because of concerns for falsification.

EPA Response. The statement that the recordkeeping would force employers to falsify records appears unsupported, because the WPS training record requirement does not require documentation of the worker's or handler's immigration status. The worker's name is the only personal identifying information required in the training record. EPA believes the requirement to provide a copy of the training record to the trained employee is reasonable and will provide adequate verification of training. If the subsequent employer does not believe that the record has been tampered with or falsified, the employer does not need to train the employee. If he or she is concerned that the record has been tampered with and potentially falsified, the employer may contact the previous establishment (listed on the record) to verify the training, or train the employee.

Comments in support of a national trained employee database. Several entities supported a national centralized database of trained workers and handlers, for a variety of purposes. A state pesticide regulatory agency expressed concern for fraudulent entries on the provided training document, and recommended that EPA develop a national database that trainers could maintain and state regulatory agencies could access to verify the training record. A state department of health also supported a centralized database of handler training, for use to determine if, in case of an incident, whether the employee was trained. Another state pesticide regulatory agency and state department of health suggested that subsequent employers could rely on the information in the database to confirm whether a new employee had been trained. Several farmworker advocacy organizations supported a nationalized central database, to estimate the number of trained workers and handlers. An academic supported the centralized tracking of training to help determine the efficacy of the training.

Another state pesticide regulatory agency would support a national database, but commented that their inspections show that most employers provide safety training even when prospective employees have verification of training, reducing the need for a federal program.

<u>EPA Response.</u> EPA discussed this alternative in the proposed rule (Ref. 2, Unit VII.B). EPA agrees that there may be merit in a centralized database of trained workers and handlers that may be

used for reference by an employer. However, EPA did not propose such a database because it is unclear whether a reliable database of national scale could be accurately populated and updated in a timely manner. Issues of who would be allowed to input data, what data would be collected, how the data would be authenticated, and who would be able to view the data, all present significant challenges. As resources permit, EPA plans to discuss with stakeholders the future feasibility, utility, and efficiency of developing and implementing a centralized database of trained workers and handlers.

Comments in opposition to a national trained employee database. Two state pesticide regulatory agencies strongly opposed a state-by-state training database, commenting that workers are very mobile and keeping the data accurate would be difficult. However, they recommended that EPA consider, in consultation with the state regulatory partners and the regulated community, the benefits of a national database. One state farm bureau and a grower opposed a requirement for worker and handler training information to be provided to the state or federal government for keeping in a central repository. They stated that during periodic regulatory inspections, there is adequate opportunity for training records to be inspected. Additional reporting burdens are not necessary. This grower also stated that the documentation can be given to workers to prove to subsequent employers that they have been trained, so the central database would not be necessary. A public health organization agreed with EPA that the cost and incremental benefit of a central database would not warrant such an undertaking. They stated that the employer records will be sufficient to demonstrate compliance.

Another grower organization commented that a national registry for training records would be very difficult to implement, stating that history has indicated that this type of verification system is extremely difficult to maintain and ensure accuracy of the information collected. A state pesticide regulatory agency commented that they did not see this providing benefits, and it would be burdensome. This entity preferred that the records be available when requested by the state. One state agency expressed concern that there would be speculation that the data would be used to track immigration status, resulting in workers' being reluctant to be trained.

<u>EPA Response.</u> EPA agrees with commenters that a national database of trained workers and handlers would be very difficult to successfully implement and would impose unnecessary burden on employers, with limited benefit.

Comment on the use of wallet-sized training verification cards. A couple of state regulatory agencies and many farmworker advocacy organizations, as well as a number of public citizens, recommended that the worker and handler training verification system include a wallet-sized card for workers and handlers, some stating because it works best in the field. The current voluntary card system relies on a wallet-sized card that is provided by the trainer or employer directly to the worker. One state pesticide regulatory agency stated that the cards serve the purpose of documenting workers' training, but noted that the current card would need to be modified to cover most of the required elements. A farmworker advocacy organization encouraged EPA to maintain the training card, stating that in their experience, employers have asked workers to sign a piece of paper indicating they had been trained, when in fact they had not. This commenter also stated that the card reinforces the importance of the training.

One crop advisor stated that the required recordkeeping is part of a well-managed operation, and asserted the elimination of the verification card is a mistake, as they are readily accepted and difficult to falsify.

One farm bureau stated that their farmers provide verification cards to their employees and contend that the proposed recordkeeping would be overly burdensome. They note that date of birth, trainer's credentials, and training materials required under the proposal are "time consuming and

restrictive." They strongly prefer the current training card. One state lead agency requested that EPA develop a training record format that could be used by employers.

EPA Response. EPA recognizes that the wallet-sized verification card is a convenient document for workers, handlers and employers. However, requiring employers to maintain training records on the establishment will allow inspectors to review two years' practices, rather than being limited to just the workers and handlers currently on the establishment. Employers would be required to provide the information on the card because of the difficulty of imposing FIFRA requirements on trainers. The WPS is applied through labeling. Since trainers are not the parties making pesticide use decisions on the establishment or making pesticide applications, requirements to comply with the WPS cannot extend to them.

The information needed to ensure that the training meets the WPS requirements would be difficult to fit on a wallet-sized card. However, if all of the information was included on a wallet-sized card, it would be sufficient documentation to comply with the recordkeeping requirement. The provision of a copy of the training record to the worker or handler provides information to subsequent employers that is complete for purposes of inspection.

<u>Comment on documentation of trainer qualifications</u>. One state regulatory agency expressed concern that they would have to maintain documentation of qualified trainers. They suggested that EPA create and maintain a national database of qualified trainers.

<u>EPA Response.</u> The requirements for qualified trainers are not different from those in the current rule; it is the responsibility of the employer to ensure the trainer has the proper qualifications. Under the final rule, the training record must include documentation of the trainer's qualification. The suggested option for a national database of qualified trainers presents similar issues as the national trained worker database discussed above, and as resources permit, EPA will include that in the stakeholder discussions about a national trained worker database. EPA notes that certified applicators must possess a credential demonstrating their qualification, which can be used to show the employer that the holder is qualified to be a trainer for workers and handlers.

Comments on access to the training record by an authorized representative. Several farm bureau organizations, one organization representative of agricultural employers, and one pesticide manufacturer organization opposed authorized representative access to training records, even if the authorization is in writing. These entities did not see any benefit and observed that there may be abuse.

<u>EPA Response</u>. EPA did not propose and is not finalizing a requirement to allow authorized representatives access to training records. Under the final rule, the designated representative (under the proposal, authorized representative) could request the application information and safety data sheet (SDS) on behalf of a worker or handler. The final rule does not require employers to make training records available to the designated representative.

Comments supporting a performance standard approach instead of recordkeeping. One public health organization recommended a performance standard that would weigh understanding of the safety principles, and highlight those training approaches that were most successful. Two farmworker advocacy organizations supported recordkeeping as a reliable, cost-efficient and effective way to determine compliance, but expressed concern that the quality of the training is important, and supported a performance standard to measure comprehension.

<u>EPA Response.</u> Inspectors having used only a performance-based approach to verifying training find the burden of interviewing each worker or handler to determine their understanding of the safety principles extremely high. Language difficulties often complicate interviews. Access to a record of training, available from the employer, provides adequate information to efficiently determine a

threshold level of compliance. EPA's guidance for inspectors recommends interviews with workers and handlers as part of the inspection, including to verify that training has been provided.

Comments opposing a performance standard to evaluate training. One state pesticide regulatory agency did not support a performance standard to evaluate training, saying it places unnecessary burden on trainers to prove their competence.

Although one public health organization supported post-testing to determine comprehension and retention, they recognized the additional cost for training and supported voluntary use of post-training assessment by employers.

<u>EPA Response.</u> EPA agrees that use of exams to determine comprehension for compliance purposes would be inappropriate with this population. There is a description of the concerns with the use of exams to evaluate training in the preamble for the proposed rulemaking (Ref. 2). EPA agrees that requiring inspectors to determine whether training was provided to a worker or handler solely through interviews and questions is inefficient, and can provide false positives and negatives.

Comments in support of a longer timeframe for record retention. One advocacy group recommended a five year retention period for records. One public health school stated that records should be kept for more than two years. A farmworker advocacy organization asserted that EPA did not adequately support a shorter timeframe rather than five years for record retention, stating that chronic illnesses can manifest years after the exposure.

<u>EPA Response.</u> EPA considered a five year retention schedule for training record retention in the proposal, but as noted in the preamble to the proposed rule, California and Florida have a two year retention timeframe (Ref. 2). EPA received support for a two year timeframe, including from state regulators who noted it would be adequate for determining compliance.

<u>Comments in support of a two year timeframe for recordkeeping.</u> One academic organization supported the two year timeframe for retention, stating that it will improve the state's ability to follow up on referrals they make on reported pesticide illness.

EPA Response. EPA agrees with this comment.

<u>Comments on state concerns for burden.</u> One state regulatory agency asked for information about how training verification will be implemented, and whether states will need to keep track of training cards. They also noted that it will be difficult to verify employee age.

<u>EPA Response</u>. EPA is not implementing a mandatory training verification card program, so states will not need to track cards. EPA plans to develop an optional form that may be used to collect the training information, but its use will not be required under the final rule. EPA is developing detailed information for the states about rule implementation. The rule becomes effective 60 days after publication, but the requirement for training recordkeeping will be implemented one year and 60 days after publication, to give states and the regulated entities time to learn and understand the rule.

Regarding the minimum age requirement for handlers and early entry workers, inspectors will need to ask how the employer verified the age of those employees, similar to the process used in liquor stores, and consider whether the method used was reasonable.

Comments from industry that civil rights laws foster employer reliance on worker-presented documents. The proposal asked whether employers would be likely to rely on training records provided by the worker. A farm bureau commenter noted it is likely that employers would rely on training records provided by the worker or handler, in part because employers are already accustomed to relying on worker-presented documents. They note that Federal law prohibits discrimination against any individual other than an unauthorized alien, with respect to hiring, employment, etc. 8 U.S.C. 1324b(a)(1). The same law expressly prohibits immigration-related discrimination by "refusing to honor

documents tendered that on their face reasonably appear to be genuine..." 8 U.S.C. 1324b(a)(6). A farm bureau made the point that since employers are accustomed to rely on presented immigration-related documents, they are also likely to rely upon WPS training documents that on their face reasonably appear to be genuine.

EPA Response. EPA thanks AFBF for the helpful information.

<u>Comment that there may be duplicative recordkeeping</u>. One grower organization suggests that there may be duplicative recordkeeping required under Food Safety Programs.

<u>EPA Response.</u> Regulations under the Food Safety Modernization Act have not yet been promulgated in final form by the Food and Drug Administration (FDA). EPA is not aware of duplicative recordkeeping requirements under FDA's proposed rules.

<u>Comment that states have requirements for recordkeeping in place.</u> One grower organization commented that EPA should reinforce the state requirements but not place additional burden by way of redundant requirements.

<u>EPA Response</u>. If state requirements produce records that satisfy the WPS requirements, inspectors can use those records to confirm compliance. If additional information is needed to satisfy the WPS requirements, employers must record that information. Moreover, under the final rule, a state or tribe may request authority to continue implementing any provision of its existing regulations (including recordkeeping requirements) that provides equivalent protection, in lieu of implementing the corresponding WPS provision.

<u>Comments in opposition to training records for handlers.</u> Several state pesticide regulatory agencies stated, in similar comments, that the recordkeeping requirements for handlers are unnecessary and would burden the handler employer:

"This section should be deleted. This extensive recordkeeping requirement for proof of training creates an unnecessary burden and expense for the agricultural producer. The current requirements in the existing rule are adequate. From a compliance standpoint, if an SLA is investigating a for-cause complaint for determination of compliance with the training requirement, examining training records alone will probably not satisfy the burden of proof for a significant enforcement action. This is especially true if any training records are found not to be 100% accurate and complete for all trainees. Again, adding this recordkeeping requirement creates the opportunity for technical violations without a demonstrated improvement in actual protections for workers and handlers. It should also be noted that since the inception of the original WPS rule [the state] has not investigated a *single complaint focusing solely* on failure to provide training. If training was not being provided, it was a case of the agricultural employer not complying with any of the WPS rule provisions."

<u>EPA Response.</u> The recordkeeping requirements for handlers are identical to the recordkeeping requirements for workers. EPA does not believe that the recordkeeping requirements for handlers impose unnecessary or excessive burdens in comparison with the expected benefits.

<u>Comment on responsibility for the training record</u>. One state pesticide regulatory agency stated that only the employer, not the trainer, should have responsibility for the record. This agency added that the record should be in paper or electronic format and retained for two years, and stated that some employers have agreements with labor contractors and the rule should allow that the entity with direction and control over the worker is the one with responsibility to keep training records.

<u>EPA Response.</u> EPA agrees that the employer is responsible for maintaining records. Trainers are not directly responsible under the rule. The employer, as the entity that makes pesticide use decisions on their establishment, is responsible for providing the protections of the rule.

Whether or not it might be desirable that the rule require labor contractors to keep training records, EPA's authority to promulgate and enforce the WPS is based on each agricultural pesticide's label requiring users to comply with the WPS. Labor contractors are not typically the pesticide user, nor do they typically have control over pesticide use on the establishment, and therefore would not ordinarily be directly subject to the WPS requirements. The employer may require, through terms of an agreement or contract, the labor contractor or other entity to prepare records of training; however, the agricultural employer is the responsible party and must demonstrate compliance.

The records may be in paper or electronic format, but they must be made available upon request for inspection purposes.

<u>Comments regarding "shift" of regulatory responsibility from EPA and states to employers for training verification for workers and handlers.</u> One state regulatory agency noted that the requirement for training verification represents a shift of regulatory responsibility from EPA and states to agricultural employers. One organization that represents agricultural employers stated the following:

"... we oppose that EPA's current proposal shifts regulatory responsibility from EPA and state lead agencies to agricultural employers, adding the cost and responsibility for implementing and maintaining a new recordkeeping system that are not considered in the Information Collection Request (ICR). Additionally it is our concern that the significantly increased documentation and retention requirements will put state lead agencies into the position that they will be sued to require them to audit such records and thus be forced to divert scarce resources from training and enforcement to become "auditors."

EPA Response. The agricultural employer is responsible, under the existing rule, to ensure that the worker or handler has been trained, according to the requirements of the rule. This final rule merely requires that the employer create a record that documents the fulfillment of that requirement. EPA expects the documentation to ease the burden on inspectors, because training can be more easily verified by reviewing a contemporaneous record than in the absence of a training record. To the extent that this represents a shifting of burden from the states (who have primary enforcement responsibility for WPS compliance) to the employer, it is a small and reasonable burden. The ICR for the proposed rule in the docket includes estimates for the recordkeeping of training on page 31, Table 14 (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0184-0105).

EPA does not expect that state lead agencies for pesticide enforcement will be sued to require them to audit training records; however, they are expected to enforce the WPS rule and as such, will be expected to inspect these records.

Comments on workers being denied employment because of lack of training record. Two farmworker advocacy organizations expressed concerns for employers denying employment to workers and handlers based on their inability to demonstrate that they have been trained.

<u>EPA Response</u>. This concern is addressed by the requirement for the employer to provide a record of their training to the requesting employee upon request. However, if the employer cannot verify that a worker or handler has been trained, they must receive the training prior to entry into a treated area.

C. Establish Trainer Qualifications for Workers and Handlers

1. Current rule and proposal. The existing WPS allows workers and handlers to be trained by a variety of persons, including pesticide applicators certified to use restricted use pesticides (RUPs) under 40 CFR part 171, persons identified by the agency with jurisdiction for pesticide enforcement as a trainer of certified applicators, or persons having completed an approved pesticide safety train-the-trainer

course. In addition, persons trained as handlers under the WPS are also eligible to train workers.

EPA proposed to limit eligible trainers of workers to those who complete an EPA-approved trainthe-trainer program or are designated by EPA or an appropriate state or tribal agency as trainers of certified applicators; being a certified applicator or trained as a handler under the WPS would not automatically qualify a person to train workers under the proposal. EPA did not propose to change the qualifications for trainers of handlers.

2. Final rule. In the final rule, EPA has expanded the class of persons qualified to train workers relative to the proposed rule. Under the final rule, qualified trainers of workers include persons who: Have completed a pesticide safety train-the-trainer program approved by EPA, are designated as a trainer of certified applicators, handlers or workers by EPA or a state or tribal agency responsible for pesticide enforcement, or are certified pesticide applicators under 40 CFR part 171. Unlike the proposal, certified applicators are considered qualified to train workers under the final rule. However, consistent with the proposal, the persons trained as handlers under the WPS are not considered qualified to train workers under the final rule.

The final rule does not make any changes from the existing rule and proposal related to who is qualified to provide training to handlers.

The final regulatory text for worker and handler trainer qualifications is available at 40 CFR 170.401(c)(4) and 170.501(c)(4), respectively.

3. Comments and responses.

Comments. Many of the comments, from states, grower organizations, and farm bureaus, advised EPA to retain certified applicators as trainers of workers in the final rule. Several commenters stated that without certified applicators providing worker training, resources such as cooperative extension trainers would be severely strained and there might not be adequate resources to provide annual training for workers. Several states and others noted that certified applicators possess the necessary competence to provide training to workers; in some states, they must receive training specifically for the purpose of training workers in order to meet their certification requirements. Commenters also questioned how a certified applicator could be considered qualified to train handlers, but not workers as many handlers have the same demographic profile as workers, some stating that the training material covered mostly the same material.

Comments that supported the proposal to remove certified applicators as trainers of workers stated that certified applicators may not have the training skills needed for effectively communicating with this demographic, but suggested certified applicators that may lack such skills could be effective trainers of workers by completing a training course.

A few commenters opposed the proposed elimination of handlers as worker trainers, stating that the existing system works and that trained handlers are needed to provide training. However, there were few comments in support of retaining handlers as trainers for workers. One comment suggested that handlers could be required to take an approved train-the-trainer course to ensure they can adequately train workers.

One commenter stated that if a certified applicator is not qualified to train a worker, then they should not be qualified to train handlers.

In response to the question raised in the proposal for the final rule regarding retraining for trainers, a few commenters suggested that refresh training should take place every five years. One commenter stated that trainers would need to know about new products and techniques that may come on line. Comments from a state and a farm bureau opposed refresh training, expressing concern for burden.

One commenter expressed concern that, if certified applicators were no longer acceptable trainers for workers, all workers would be trained as handlers to manage the additional training requirements, and they would perform handler tasks with higher risk.

One commenter suggested that EPA designate a category under the Certification of Pesticide Applicators rule for WPS Trainers. Persons certified under this category would be eligible to train workers.

<u>EPA Response.</u> EPA is persuaded by the comments that it is reasonable to expect that certified applicators can competently train workers, as well as handlers. Commenters noted that certified applicators possess knowledge of pesticide safety from their certification training and pesticide handling experience. The commenters stated that the additional burden from the proposed requirement for annual training in combination with the elimination of certified applicators as trainers would severely strain trainer resources and potentially result in fewer workers receiving annual training. This concern persuaded EPA to include certified applicators as qualified to train workers in the final rule.

Commenters that supported the proposal to no longer qualify all certified applicators as trainers of workers recommended that they receive training to qualify as trainers. This is very similar to the proposal that would have allowed certified applicators to train workers if they completed a train-the-trainer course. In combination with concerns raised for burden in response to the question about refresh training for trainers, and the consistent comments from states and growers supporting certified applicators as trainers of workers, EPA was convinced that certified applicators have successfully trained workers since the rule was originally implemented and should continue to be eligible to provide training to workers.

In response to comments supporting handlers as trainers of workers, EPA is not convinced that they possess the skills and/or technical knowledge to convey the information. Some comments stated that the existing system works and that trained handlers are needed to provide training. EPA believes that permitting certified applicators to train workers provides adequate numbers of trainers. Under the final regulation, any person, including a handler, is qualified to train workers after successfully completing an approved train-the-trainer course.

In response to concerns that without certified applicators as trainers of workers, more workers would be given handler training and thereafter perform handler tasks with higher risk, EPA does not consider this a plausible outcome, but it is moot as the final rule allows certified applicators to train workers. First, EPA expects that the difference between the burdens of worker and handler training will encourage the development of appropriate worker training capacity. Second, an increase in the number of trained handlers would not increase risk, because it would not cause an increase in the aggregate hours of handler activity; if there were an increase in the number of trained handlers, that would merely spread those hours over a larger pool of trained handlers.

EPA agrees with the commenters that requiring refresher training for trainers would be burdensome. Although application methods and pesticides used might change over time, the pesticide safety training provides common-sense steps that workers can take to protect themselves from exposure, and EPA does not find that these steps change significantly over time. EPA supports training for trainers and encourages them to enhance their skills, but based on comments received, has not established a requirement under the WPS for refresher training for trainers of workers or handlers.

The comment that EPA should establish a category under the Certification of Pesticide Applicators rule for certified applicators to become qualified as WPS worker trainers is moot because under the final rule, any certified applicator is authorized to train workers.

1114	In response to the question of whether a person trained as a handler is allowed to perform
1115	worker activities without separate worker training, EPA agrees that a person trained as a handler is
1116	qualified to perform worker activities. The question of what would have been allowed under the
1117	proposed rule is moot.
1118	D. Expand the Content of Worker and Handler Pesticide Safety Training
1119	1. Current and proposed rule. The existing WPS requires employers to provide pesticide safety
1120	training covering specific content to workers and handlers. Under the existing rule, worker safety
1121	training content must include the following 11 points:
1122	 Where and in what form pesticides may be encountered during work activities.
1123	 Hazards of pesticides resulting from toxicity and exposure, including acute and chronic
1124	effects, delayed effects, and sensitization.
1125	 Routes through which pesticides can enter the body.
1126	 Signs and symptoms of common types of pesticide poisoning.
1127	 Emergency first aid for pesticide injuries or poisonings.
1128	How to obtain emergency medical care.
1129	Routine and emergency decontamination procedures, including emergency eye flushing
1130	techniques.
1131	Hazards from chemigation and drift.
1132	Hazards from pesticide residues on clothing.
1133	 Warnings about taking pesticides or pesticide containers home.
1134	 Requirements of the WPS designed to reduce the risks of illness or injury resulting from
1135	workers' occupational exposure to pesticides, including application and entry restrictions,
1136	the design of the warning sign, posting of warning signs, oral warnings, the availability of
1137	specific information about applications, and the protection against retaliatory acts.
1138	Under the existing rule, pesticide handler safety training must include the following 13 basic
1139	safety training points:
1140	 Format and meaning of information contained on pesticide labels and in labeling, including
1141	safety information such as precautionary statements about human health hazards.
1142	 Hazards of pesticides resulting from toxicity and exposure, including acute and chronic
1143	effects, delayed effects, and sensitization.
1144	Routes through which pesticides can enter the body.
1145	 Signs and symptoms of pesticide poisoning.
1146	Emergency first aid for pesticide injuries or poisonings.
1147	How to get emergency medical care.
1148	Routine and emergency decontamination procedures.
1149	Need for and appropriate use of PPE.
1150	 Prevention, recognition, and first aid treatment of heat-related illness.
1151	 Safety requirements for handling, transporting, storing, and disposing of pesticides.
1152	• Environmental concerns.

• Warnings about taking pesticides or pesticide containers home.

• Training on the requirements of the regulation related to handling.

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EPA proposed additional content in worker pesticide safety training including, among other things, information on the requirements for early-entry notification and emergency assistance, how to reduce pesticide take-home exposure, the availability of hazard communication materials for workers, the minimum age requirements for handling and early entry, and the obligations of agricultural employers to provide protections to workers.

EPA proposed additional content in handler pesticide safety training, including the requirement for handlers to cease application if they observe a person, other than another trained and properly equipped handler, in the area being treated or the entry-restricted area, and information about the requirement for OSHA-equivalent training on respirator use, fit-testing of respirators, and medical evaluation in the event a handler must wear a respirator.

2. Final rule. EPA has finalized the proposed additions to and expansions of the worker and handler pesticide safety training. The final regulatory text for the content of worker and handler pesticide training is available at 40 CFR 170.401(c)(2)-(3) and 170.501(c)(2)-(3).

The final rule requires employers to ensure that workers are trained on the following topics after EPA has announced the availability of training materials (see Unit XIX. for information on the timing of implementation):

- The responsibility of agricultural employers to provide workers and handlers with information and protections designed to reduce work-related pesticide exposures and illnesses. This includes ensuring workers and handlers have been trained on pesticide safety, providing pesticide safety and application information, decontamination supplies and emergency medical assistance, and notifying workers of restrictions during applications and on entering pesticide treated areas. A worker or handler may designate in writing a representative to request access to pesticide application and hazard information.
- How to recognize and understand the meaning of the warning sign used for notifying workers of restrictions on entering pesticide-treated areas on the establishment.
- How to follow directions and/or signs about keeping out of pesticide-treated areas subject to an REI and application exclusion zones.
- Where and in what form pesticides may be encountered during work activities and potential sources of pesticide exposure on the agricultural establishment. This includes exposure to pesticide residues that may be on or in plants, soil, tractors, application and chemigation equipment, or used PPE, and that may drift through the air from nearby applications or be in irrigation water.
- Potential hazards from toxicity and exposure that pesticides present to workers and their families, including acute and chronic effects, delayed effects, and sensitization.
 - Routes through which pesticides can enter the body.
 - Signs and symptoms of common types of pesticide poisoning.
 - Emergency first aid for pesticide injuries or poisonings.
- Routine and emergency decontamination procedures, including emergency eye flushing techniques, and if pesticides are spilled or sprayed on the body, to use decontamination supplies to wash immediately or rinse off in the nearest clean water, including springs, streams, lakes, or other sources, if more readily available than decontamination supplies, and as soon as possible, wash or shower with soap and water, shampoo hair, and change into clean clothes.
 - How and when to obtain emergency medical care.
- When working in pesticide-treated areas, wear work clothing that protects the body from pesticide residues and wash hands before eating, drinking, using chewing gum or tobacco, or using the toilet.

- Wash or shower with soap and water, shampoo hair, and change into clean clothes as soon as possible after working in pesticide-treated areas.
 - Potential hazards from pesticide residues on clothing.

- Wash work clothes before wearing them again and wash them separately from other clothes.
- Do not take pesticides or pesticide containers used at work to your home.
- Safety data sheets provide hazard, emergency medical treatment and other information about the pesticides used on the establishment they may come in contact with.

The responsibility of agricultural employers to do all of the following: Display safety data sheets for all pesticides used on the establishment, provide workers and handlers information about the location of the safety data sheets on the establishment, and provide workers and handlers unimpeded access to safety data sheets during normal work hours.

- The rule prohibits agricultural employers from allowing or directing any worker to mix, load or apply pesticides or assist in the application of pesticides unless the worker has been trained as a handler.
- The responsibility of agricultural employers to provide specific information to workers before directing them to perform early-entry activities. Workers must be 18 years old to perform early-entry activities.
 - Potential hazards to children and pregnant women from pesticide exposure.
 - Keep children and nonworking family members away from pesticide-treated areas.
- After working in pesticide-treated areas, remove work boots or shoes before entering your home, and remove work clothes and wash or shower before physical contact with children or family members.
- How to report suspected pesticide use violations to the state or tribal agency responsible for pesticide enforcement.
- The rule prohibits agricultural employers from intimidating, threatening, coercing, or discriminating against any worker or handler for complying with or attempting to comply with the requirements of this rule, or because the worker or handler has provided, caused to be provided, or is about to provide information to the employer or to the EPA or its agents regarding conduct that the employee reasonably believes violates this part, and/or has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing concerning compliance with this rule.

The final rule requires employers to ensure that handlers are trained on the following topics after EPA has announced the availability of training materials (see Unit XIX. of the preamble for information on the timing of implementation):

- All content for worker training.
- Information on proper application and use of pesticides.
- Handlers must follow the portions of the labeling applicable to the safe use of the pesticide.
- Format and meaning of information contained on pesticide labels and in labeling applicable to the safe use of the pesticide.
 - Need for and appropriate use and removal of all PPE.
 - How to recognize, prevent, and provide first aid treatment for heat-related illness.
- Safety requirements for handling, transporting, storing, and disposing of pesticides, including general procedures for spill cleanup.
 - Environmental concerns, such as drift, runoff, and wildlife hazards.
 - Handlers must not apply pesticides in a manner that results in contact with workers or other

1245 persons.

- The responsibility of handler employers to provide handlers with information and protections designed to reduce work-related pesticide exposures and illnesses. This includes providing, cleaning, maintaining, storing, and ensuring proper use of all required personal protective equipment; providing decontamination supplies; and providing specific information about pesticide use and labeling information.
- Handlers must suspend a pesticide application if workers or other persons are in the application exclusion zone.
 - Handlers must be at least 18 years old.
- The responsibility of handler employers to ensure handlers have received respirator fit-testing, training and medical evaluation if they are required to wear a respirator by the product labeling.
 - The responsibility of agricultural employers to post treated areas as required by this rule.

EPA intends to develop the training materials that meet the final training requirements and to publish in the Federal Register a notice of their availability. To allow time for the completion and distribution of revised training materials and to allow time for trainers to become familiar with them and begin training workers and handlers, the rule extends the implementation period for training on the new requirements for two years, or until six months after EPA has made the revised training materials available, whichever is longer. The final requirements for the content of worker and handler pesticide safety training are available at 40 CFR 170.401(c)(2)-(3) and 170.501(c)(2)-(3), respectively.

3. Comments and responses.

<u>Comments on training requirements – general.</u> Farmworker advocacy organizations, many states, and public health organizations provided support for the expanded training topics, in particular information about preventing take-home exposure, and medical evaluation, fit testing and training on respirator use for handlers who need to wear respirators. Some farmworker advocacy organizations commented on the importance of information about worker rights.

Agricultural producer organizations expressed concern for the additional burden of the lengthier training. Some states asserted that several of the handler training points are beyond the scope of the WPS and should be addressed in applicator certification only. Specifically, they requested that EPA eliminate training on environmental concerns from pesticide use; proper application and use of pesticides; and requirements for handlers to understand the format and meaning of all information contained on pesticide labels and labeling, and to follow all pesticide label directions. These commenters stated that these training points are appropriate for persons who work under the supervision of certified applicators, but they do not relate directly to worker or handler safety. Two states recommended a revision to language in the handler training topics requiring that "all" information on the pesticide label would be required to be covered, stating that all labeling information may not be relevant to a given application.

EPA Response. EPA does not agree with comments from states that the handler training topics related to environmental concerns from pesticide use, proper application and use, requirements for handlers to understand the format and meaning of information on labeling and to follow labeling directions are beyond the scope of the WPS and may expand the liability of handlers. First, the "Worker Protection Standard" title is descriptive, and not jurisdictional. The WPS is, in essence, a codification of material that EPA would otherwise have to require to appear on the labeling of agricultural pesticides. Thus its potential scope is as broad as EPA's labeling authority. While there may be some point at which a prospective provision might be so tangentially related to the rest of the WPS that its inclusion in the WPS would cause excessive confusion, that is not the case with the provisions included in today's final

1290 rule.

In addition, this is not the first time that requirements included in the WPS have served purposes beyond the protection of agricultural workers and handlers. Section 170.210(a) of the existing rule requires that "The handler employer and the handler shall assure that no pesticide is applied so as to contact, either directly or through drift, any worker or other person, other than an appropriately trained and equipped handler" (emphasis added). Section 170.234(c) of the existing rule requires that, among other things, when application equipment is sent to non-handlers for repair, the handler employer must assure that pesticide residues have been removed, or else warn the person who would perform the repair. The handler training point on environmental concerns from pesticide use already appears in the existing rule at 40 CFR 170.230(c)(4)(xi). In response to a similar comment on the proposal that resulted in the existing regulation, EPA stated:

One comment questioned the relevancy of environmental information in worker protection training. The Agency believes such training is relevant to worker protection. Many environmental concerns are applicable not only to the organisms in the environment, but also to workers and other persons who may be in that environment. Ground and surface water warnings, for example, are designed not to protect only aquatic organisms, but to protect workers and other persons who may be using the water for drinking, cooking, bathing, etc. The Agency notes that FIFRA defines "environment" as including "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." (Ref. 8).

The final rule retains the requirement for handler training on environmental concerns related to pesticide use from the current WPS.

EPA does not agree that the training topic requiring handlers to receive instruction on proper application and use of pesticides is only appropriate for noncertified applicators making application under the direct supervision of a certified applicator. First, handlers routinely apply pesticides, and misapplication of pesticides can result in injury to persons covered by the WPS, including workers and handlers. Training on proper use can help prevent such misapplication and consequent exposure to people. Second, relying solely on the training of noncertified applicators under direct supervision would cover only applicators using RUPs, and many agricultural use products covered by the WPS are not RUPs. To ensure that handlers under the WPS have the training to apply pesticides properly, it is necessary for them to be trained on proper use. The final rule includes the handler training topic requiring information on proper application and use of pesticides.

EPA does not agree with the commenters that requirements for handlers to understand the format and meaning of information on labeling and to follow labeling directions are only appropriate for noncertified applicators applying under the supervision of certified applicators. To properly handle agricultural pesticides covered by the WPS rule, handlers need to understand the information on the labeling related to safe use of the pesticide and follow the use instructions. Use of a product in a manner inconsistent with the labeling may cause injury or illness to the handler and to others. However, EPA did revise the handler training requirements based on commenters concerns that the proposed training requirements were too broad. See the discussion in Unit XVIII.A. related to changes to the handler training requirements covering labels and labeling.

<u>Comments on the cost.</u> A farm bureau expressed concern for the costs of revising and updating existing materials, questioning whether the additional material is necessary to further the program and whether it can be provided in a way that it can be used.

EPA Response. EPA agrees that there are costs associated with the revisions to the training

program, including costs to update materials, produce, and distribute them. EPA plans to revise the training materials and make them widely available, reducing the burden on employers. EPA has considered the costs to the regulated community and found them to be reasonable in the context of health improvements and protections for workers, handlers, and their families.

<u>Comment on applicability of information</u>. One commenter stated that the CDC study cited in the preamble does not reflect current practices, and that since the 1996 FQPA, there have been significant revisions to pesticide regulation.

EPA Response. Families and their environment can be exposed to pesticides by contact with residues carried on working parents' clothing, dirt tracked into the home, or from other pathways. The transfer of residues can be minimized by the worker or handler by observing simple hygienic steps, including hand washing and removal of work boots prior to entry into the home. Studies cited in the preamble demonstrated a reduction in residues when workers observe these practices. Although the CDC study itself is from 1995, several of the studies that support improved practices to reduce take home exposure are more recent, notably the 2000 study by Lu, et al, titled "Pesticide Exposure of Children in an Agricultural Community: Evidence of Household Proximity to Farmland and Take Home exposure Pathways," and the Arcury study titled, "Pesticide Urinary Metabolite Levels in Urine of Children Living In Agricultural Communities (2005)." These studies found that children in homes with agricultural parents are exposed to pesticides and that changes are needed to protect them from such exposures.

Although the FQPA has altered the types and amounts of certain pesticides used on certain crops in order to reduce dietary exposures, there is no evidence that it has resulted in overall reductions in worker or handler occupational exposure to pesticides or the associated risks.

Comments on topics related to reporting violations. Two commenters expressed concern for EPA's rationale to require worker and handler pesticide safety training to include information on how to report suspected pesticide use violations. They objected to the rationale in part because the context used to justify this action suggested that it is an infringement of "WPS rights", not general pesticide or FIFRA label violations.

<u>EPA Response.</u> EPA believes the commenters have misunderstood EPA's position. The proposal states the following related to this issue:

"Farmworker advocacy organizations recommend including in the worker or handler pesticide safety training information on the rights of workers and handlers under the WPS (Ref. 36). The Agency agrees that workers and handlers should be aware of WPS provisions on how to report violations and the prohibition on retaliation by the agricultural employer." (Ref. 2.)

While the WPS does not use the term "rights", various sections (particularly section 170.7 of the existing WPS) impose certain duties upon employers in regard to their employees, and it is not unreasonable to speak of employees having certain WPS rights as a consequence of the employers' WPS duties. However, the commenters appear to misconstrue the preamble statement as an endorsement of broader worker rights claims made by farmworker advocates. Regardless of what other rights workers and handlers might have, EPA's focus is on compliance with FIFRA and its associated regulations and requirements. Consequently, the focus of the WPS training provision concerning reporting of violations refers to pesticide use violations (including WPS violations).

<u>Comments on "take home exposure" training.</u> One commenter wrote at length about "protection from pesticide take home exposure," stating that current training already addresses the risks of pesticide residues on clothes, and this awareness could be augmented quite simply by updating

current training materials. It does not warrant the attention paid to it within the preamble. The commenter expressed concern that the tone and information provided by EPA to justify this action undermines the great strides that have been made in product safety, labeling and application.

<u>EPA Response.</u> The existing point in the training informs workers and handlers to remove and wash their clothes to protect themselves from exposure to pesticide residues. The additional training point emphasizes that there are risks to worker's families from these residues, and provides information on how to reduce those exposures. EPA agrees that updates to the training are necessary.

<u>Comments on handler training</u>. One commenter recommended that NIOSH and OSHA be involved with EPA's review of training material. They ask if the employer can rely on outside trainers to provide the respirator training, or have these agencies approve materials.

<u>EPA Response</u>. The training requirements of the WPS for handlers wearing respirators must conform to 29 CFR 1910.134. EPA plans to work with NIOSH and OSHA on the development of training material related to respirators. The final rule requires employers to ensure proper respirator training conforming to 29 CFR 1910.134 is provided for handlers required to wear a respirator; it does not prohibit the employer from using outside trainers to provide the required respirator training.

E. Exception to Full Pesticide Safety Training for Workers Prior to Entry into Treated Areas (Grace Period).

- 1. Current rule and proposal. Except in regard to workers entering treated areas during an REI, the existing WPS permits the agricultural employer to delay providing full pesticide safety training until the end of the fifth day after the worker's entry into a treated area, often called the "grace period," provided that the worker receives training in a basic set of two safety points before entering the treated area (i.e., an area that has been treated or where an REI has been in effect within the last 30 days). Under this exception, the worker must receive the full safety training on the content outlined in the rule prior to the sixth day of entry into a treated area. EPA proposed to shorten the "grace period" to two days, require that full training take place before the third day of entry into a treated area, and expand the basic set of safety information to be provided prior to the worker's first entry into a treated area under the "grace period."
- 2. Final rule. EPA has eliminated the "grace period" entirely. The final rule requires employers to ensure that workers receive full pesticide safety training before entering a treated area (i.e., an area that has been treated or where an REI has been in effect within the last 30 days).
 - 3. Comments and responses.

Comments. Few commenters supported the proposed two day grace period coupled with the expanded basic safety points prior to first entry. Many agricultural producer organizations and the SBA Office of Advocacy requested that EPA retain the five day grace period in the existing rule, stating it is needed for flexibility in scheduling training sessions as workers arrive at various times on the establishment. Many farmworker advocacy organizations and two states recommended elimination of the grace period entirely. Several commenters recommended, as an alternative, adoption of the two day grace period with reduced material relative to the proposed training required prior to first entry, because the brief training seemed onerous. Farmworker advocacy organizations that supported the elimination of the grace period cited the importance of workers having full safety information prior to entering an area with pesticide residues. One state that supported the elimination of the grace period expressed concern that this change would heighten concerns about the number of qualified trainers in the event that EPA would follow through on its proposal to make certified applicators ineligible to train workers.

SBA's Office of Advocacy stated that small businesses stated that a reduced grace period would require employers to hire workers earlier and increase the per-hire costs. Other small businesses stated

that flexibility is needed around busy schedules and to ensure continuity of operations.

Two commenters from regulatory agencies in states with significant agricultural production stated that their programs do not allow a training grace period; in those states, workers must be trained before they can enter treated areas. Some commenters indicated that eliminating the grace period would reduce complexity of the rule.

EPA Response. While EPA recognizes the flexibility that the grace period offers agricultural employers in scheduling training sessions for workers, and the economic importance of that flexibility, EPA remains convinced that the elimination of the grace period is reasonable. The full pesticide safety training provides information that workers need to have before their exposure to pesticide treated areas so they can protect themselves. Under OSHA, training must take place at the time of the employee's initial assignment. EPA has decided that the cost of eliminating the grace period is reasonable when compared to the benefit from workers receiving the complete pesticide safety training before their first exposure to pesticides.

EPA acknowledges concerns raised by agricultural producer organizations and state regulatory agencies that eliminating the grace period combined with the proposal to limit who is qualified to conduct worker training could result in an inadequate number of people available to provide worker training. The final rule allows certified applicators to continue to be trainers of workers (see Unit V.D.). As a result, EPA expects that there will be an adequate number of trainers to provide full pesticide safety training for workers prior to their entry into treated areas.

F. Training Program Administration Requirements

- 1. Current rule and proposal. Under the existing WPS, pesticide safety training must be presented either orally from written materials or in audiovisual format. The information must be presented in a manner that the worker or handler can understand, and the trainer must respond to questions, but the existing rule does not require the trainer to be present for the entire training period. EPA proposed to retain the requirement to provide training in an oral or audiovisual format, to require that the trainer remain present throughout the training session, and to require that the training be presented in a place that is conducive to learning and reasonably free of distractions.
- 2. Final rule. EPA has finalized the proposed requirements for the presentation of training. Trainers of workers and handlers must remain present during training sessions to respond to questions. The training environment must be conducive to training and be reasonably free of distractions, to help ensure training quality. The final rule retains the existing requirement for pesticide safety training to be delivered either orally from written materials or by audiovisual means.

The final regulatory text for these requirements is available at 40 CFR 170.401(c)(1) and 170.501(c)(1).

3. Comments and responses.

Comments on use of videos. Most commenters endorsed the use of videos. Some stated that they enhance understanding of the material, especially when combined with hands-on activities or other kinds of learning approaches. Other farmworker advocacy organizations stated that there is a lack of interaction between the trainer and the employees trained using a video, resulting in reduced information transfer. Agricultural producer organizations and state regulatory agencies supported the use of the video, citing ease of use and effectiveness. Commenters from each category urged EPA to update the videos; a few suggested EPA evaluate different media presentations.

One commenter noted that videos are preferred so the workers and handlers can see and hear the presentation. This commenter mentioned that trainees preferred having the presenter remain with the workers to answer questions and manage distractions.

Another commenter suggested that trainers use a variety of materials, including the videos, to train and cited the Food Safety training materials that are adapted to field situations and include flip charts, handouts, and videos. One department of agriculture recommended keeping the video because employers would not need expertise to provide the training. They suggested having two videos, one for entry level and one for more experienced workers. Another state regulatory agency stated that the video is an essential training tool.

Many other organizations – growers, pesticide manufacturers, and farm bureaus – supported the use of the video for training.

<u>EPA Response.</u> EPA agrees with the commenters who consider videos to be effective and useful training materials.

EPA intends to update the training videos with information about the final rule requirements. The revised videos will cover updates to the rule as well as the existing protections. EPA recognizes that updated videos are needed for workers and handlers.

Comments on the requirement for trainers to remain present during entire training session. Farmworker advocacy organizations and another commenter supported the proposal for trainers to remain present during the entire training, citing the need for them to be interactive with workers to enhance the training and facilitate discussion. One commenter, experienced in providing pesticide safety training, noted that the interaction with trainees, through hands-on training and sharing of experiences, was effective. Some agricultural producer organizations opposed the requirement, stating that it would be distracting for the video to be interrupted for questions, and there would be lost time for the trainer. One commenter suggested it would lead to larger training conferences that would discourage post-video interaction. Some states opposed the requirement for the trainer to be present throughout the training; some recommended that the trainer only needs to be available before and/or after the training if a video is used.

One pesticide manufacturer organization supported requiring the trainer to remain present during the training, but other agricultural industry organizations rejected the concept, stating that it was burdensome and unnecessary, and that the trainer was only needed at the end or beginning of the training.

Workers responding to questions from an advocacy organization indicated that having persons available to answer questions was important.

<u>EPA Response.</u> EPA agrees with the commenters that having trainers present during the entire training program could facilitate discussion and promote interaction. EPA recognizes that a video is a passive form of training, and has added the requirement for the trainer to be present to answer questions during the entire session to mitigate this problem.

EPA disagrees that questions from the trainees would be disruptive to the training; responding to questions during the video would facilitate learning. A 2006 study (Burke) cited interactive training activities as a best practice for supporting training transfer. EPA is convinced that the trainer's presence during the video enhances the training by enabling questions and discussion during the presentation.

Comments on the requirement for the training environment to be relatively free of distractions and conducive to learning. The commenters were mostly in agreement that the learning environment needs to have minimal distractions and be conducive to learning. Farmworker advocacy organizations and public health organizations supported the proposed requirement as a way to improve the learning environment. Two farm bureaus suggested allowing the trainer to be absent during the video, and to have a supervisor present to ensure the quality of the training environment. One state supported the proposed requirement for the training to be conducted in an environment reasonably free of

distractions; another stated that the requirement was not enforceable. Finally, one agricultural organization described the environment where their workers receive training as taking place either on or outside their transportation bus or in the field where it is difficult to manage distractions, and noted that the low number of incidents is evidence that the training is effective.

EPA Response. EPA agrees that the requirement for the training environment to be reasonably free from distractions and conducive to training would make it easier for workers and handlers to absorb and retain information. As discussed in the previous response, EPA disagrees with comments requesting that EPA eliminate the requirement for the trainer to be present throughout the training. The proposal and final rule establish requirements for the training location; the ultimate responsibility for ensuring the requirements are met rests with the employer. EPA recognizes that there are challenges in locating environments in agriculture that are quiet and present few distractions; classrooms are rarely convenient. However, EPA is requiring employers to provide a training environment that is reasonably free from distractions and conducive to training. EPA notes that the final rule does not prohibit providing training in any specific location, such as outdoors or on a bus, as long as the environment is reasonably free from distraction and conducive to training.

Other comments on training administration. Commenters from a state regulatory agency and farmworker advocacy organization suggested that the trainings should be in the language of the workers and/or handlers.

EPA Response. EPA agrees that, ideally, trainers would provide training in the language of the workers or handlers. Agricultural workers and handlers speak many languages, and employers may not have ready access to trainers with skills in multiple languages. The WPS requires that the training be provided in a manner that the worker or handler can understand, which allows flexibility for the trainer to use graphics, gestures, and examples to describe a point. The concepts from the training are relatively simple and can be communicated with the use of a narrated video or pictorial flipchart, along with demonstrations by the attending trainer.

- G. Require Employers to Provide Establishment-Specific Information to Workers and Handlers
- 1. Current rule and proposal. The existing WPS does not clearly require employers to provide to workers and handlers establishment-specific information on the location of decontamination supplies or hazard information as part of their pesticide safety training. EPA proposed that in addition to required pesticide safety training, employers must provide workers and handlers with establishment-specific information about the location of decontamination supplies and pesticide safety and hazard information, as well as how to obtain medical assistance. EPA proposed that agricultural and handler employers would be required to provide this establishment-specific information to all workers and handlers, including those previously trained on other establishments.
- 2. Final rule. EPA has finalized the proposed requirement for employers to provide establishment-specific information to workers and handlers. The final rule requires employers to provide establishment-specific information for workers and handlers when they enter the establishment and before beginning WPS tasks in areas where within the last 30 days a product requiring compliance with the WPS has been applied or an REI has been in effect. Content for the establishment-specific information includes the location of the pesticide safety information, the location of pesticide application and hazard information, and the location of decontamination supplies. Employers are required to provide this information in a manner that the worker or handler can understand, such as through a translator, and prior to the worker or handler performing activities covered by the WPS. Lastly, this information is required even if the employer can verify that the worker or handler has already received the general pesticide safety training on another establishment, because the

information required is specific to each establishment. The final regulatory text for these requirements is available at 40 CFR 170.403 and 170.503(b).

3. Comments and responses.

<u>Comments.</u> Most commenters supported the addition of the establishment-specific training, with some noting that it is currently being provided voluntarily. One farmworker advocacy organization commented that the information would help workers access decontamination supplies and safety and hazard information quickly, even workers trained at other establishments.

Some farm bureaus, a grower organization, and a state pesticide regulatory agency noted that employers already provide the information, and another farm bureau stated that the requirement is reasonable.

One grower organization requested clarification on whether the statement in the preamble about "how to obtain emergency medical assistance" refers to emergency numbers on the safety poster.

Two farmworker advocacy organizations responded to a question in the preamble, that asked if there are any issues related to the requirement that the information be provided in a manner the worker or handler understands. These farmworker advocacy organizations replied that the information needs to be in the worker's or handler's "mother tongue." Similarly, another farmworker advocacy organization stated that the requirement must establish that the information be provided in a language all workers can understand fluently; it must be delivered at an appropriate literacy level and in a culturally appropriate manner. Additionally, the commenter stated that the content must include information about buffers in the fields.

One commenter expressed concern that the training has to be EPA-approved and must be presented in a manner the worker can understand such as through a translator, and that this could increase costs.

One state regulatory agency stated that this requirement should be deleted, because the provision does not specifically address protection of workers, is not germane, and therefore should not be included in this rule. A commenter representing agricultural industry stated that employers must provide workers with information on restricted sites.

<u>EPA Response.</u> EPA agrees with the commenters that the establishment-specific training is necessary for workers and handlers to know where to find information on the establishment to protect themselves from pesticides and their potential effects. EPA notes that some of this information is required under the existing rule. However, EPA is convinced that consolidating the requirements for establishment-specific training and co-locating them with requirements for pesticide safety training will make them easier for employers to find and comply with, resulting in a higher likelihood that workers and handlers will receive the necessary information.

One commenter requested clarification of the meaning of the phrase "how to obtain emergency medical assistance." To clarify, the establishment-specific training requirement includes the location of the safety information display, which provides contact information for emergency medical services. Once the worker or handler knows where to access the safety information, they can contact emergency medical assistance. In addition, if a worker or handler may have been exposed or displays symptoms consistent with pesticide exposure, their employer is obligated to provide emergency assistance under the rule. This point is covered in pesticide safety training.

Two commenters were concerned that the training would have to be EPA-approved. The worker training covered under Section 170.401 and the handler training under 170.501 must be approved by EPA, however, the establishment-specific training is not required to be EPA-approved. EPA

believes the requirements themselves are self-explanatory. Please refer to 170.403 and 170.503(b) for the regulatory language.

One of the commenters expressed concern that the information had to be provided in a manner that the worker or handler can understand, such as through a translator, stating that it could increase costs. For the information to be useful it must be provided so the worker or handler can understand it. However, EPA recognizes that there are many languages spoken by farmworkers and does not require that the information is provided in those languages. Information may be provided through videos, illustrations, and gestures in such a way as to be understood by the target audience.

Regarding the comments from farmworker advocacy organizations about the need for the information to be provided in the language of the worker or handler, EPA agrees that this would be useful. However, there are many languages spoken by workers and handlers, and the burden on employers to find translators for this information, in a timely manner, would be too great. Also, the existing requirement for training to be provided so the employee can understand it has been in the rule for training for nearly 20 years without significant problem. This, combined with comments from growers that the information is already being provided, suggests that employees are receiving the information and understanding it. Trainers may rely on videos in the language of the workers or a flipchart to share information.

Regarding the comment about presenting the information in a culturally appropriate way and at a literacy level that could be understood by the employee, EPA expects that the location of the decontamination supplies, the safety poster, and the hazard information is not likely to be provided in a manner that would be inappropriate or difficult to understand.

Regarding the comment about the employer providing information about buffers in the field, EPA believes the commenter was referring to the application exclusion zone (previously the entry restricted area). EPA considered this requirement, but rejected it because under the final rule, it is only a requirement during the application, the temporal nature of the restriction would limit the usefulness of the information, and would be difficult to convey accurately. Finally, the annual safety training includes information on restrictions during application, so workers will know to stay away from areas during treatment.

EPA disagrees with the comment that the establishment-specific information does not contribute to worker or handler safety. As commenters have noted, knowing where to go to decontaminate, find safety and hazard information, and learn what they were exposed to, can enable workers and handlers to reduce their exposure, find ways to avoid exposure, and react to an exposure by contacting an emergency medical facility.

VI. Notification

A. Posted Notification Timing and Oral Notification

1. Current rule and proposal. The current WPS requires agricultural employers to notify workers about pesticide applications and areas on the agricultural establishment subject to an REI. Notification is required when workers are on the establishment during application or the REI and will pass within one-quarter mile of the treated area. On farms, and in forests and non-enclosed nurseries (referred to as "outdoor production" in the proposal) the agricultural employer may choose either to post warning signs at the usual points of entry around the treated area or to notify workers orally about applications that will take place on the establishment. In greenhouses and some other enclosed spaces (referred to as "enclosed space production" in the proposal), the agricultural employer must post warning signs for all applications, regardless of the product's REI. In cases where the product labeling requires both written and oral notification of workers, the WPS also requires this "double notification."

For outdoor production, EPA proposed requiring agricultural employers to post warning signs where the pesticide to be applied has an REI greater than 48 hours, and to allow the option of oral warning or posted notification for products with an REI of 48 hours or less. For enclosed space production, EPA proposed requiring posting of warning signs only when the product applied has an REI greater than four hours, and to allow the option of oral warning or posted notification for products with an REI of four hours or less.

2. Final rule. EPA has finalized the proposed requirements to post warning signs for all "outdoor production" when a product with an REI longer than 48 hours is used, and to allow either oral or posted warnings for "enclosed space production" when a product with an REI of 4 hours or less is used. The final regulatory text for these requirements is available at 40 CFR 170.409(a)(1)(ii)-(v). The final rule modifies the existing requirement for employers to take down posted warning signs within three days of the expiration of the REI by prohibiting worker entry into the area until the posted warning signs have been removed (except for early entry pursuant to 40 CFR 170.603). The final regulatory text for this prohibition is available at 40 CFR 170.409(b).

3. Comments and responses.

<u>Comments in support of proposal.</u> Many states and some farmworker advocacy organizations and public health organizations supported the notification requirements as proposed. They noted the potential benefit to workers and employees of crop advisors of mandatory posting for the most toxic pesticides. They agreed with EPA's assessment that additional posting would provide added protection for workers while placing a minimal burden on employers.

Comments opposed to the proposal. Several grower associations and farm bureaus supported the proposed change in notification requirements for indoor production but opposed the proposal for additional posting for outdoor production. They noted that signs can be destroyed, removed, or relocated and that agricultural producers may not return to some fields more than once per week. One grower association specifically requested that EPA clarify how enforcement would address these challenges. Another grower association highlighted the need for clarity on how to comply with notification rules for products with multiple, activity-based REIs. One grower association also stated that workers are fully capable of understanding oral notification and suggest focusing instead on reinforcing the existing oral notification. One industry association objected to the proposal on the grounds that the changes did not recognize existing practices and improvements in training, recordkeeping, supervision and other protections since the WPS was initially implemented. This commenter also noted that posting for REIs is further complicated by the additional requirement to post "no entry" buffers during application. Several grower associations stated that the proposal lacked data to support the need for increased posting or for why certain REIs were selected over others, and that EPA underestimated the cost of field posting.

Comments suggesting alternatives to the proposal. Several farmworker advocacy organizations, health organizations, individual farmworkers and one state regulatory agency suggested requiring both posting signs and providing oral warnings for all pesticide applications, or at a minimum for those pesticides with an REI of 12 hours or more. Some farmworker advocacy organizations suggested mandatory posting of any treated area subject to an REI greater than 24 hours, and others requested that EPA require mandatory posting of any treated area subject to an REI. They reiterated EPA's rationale that oral notification of pesticide application information is difficult to recall over multiple days, that oral notification may not be clearly communicated due to multiple language barriers and that it is difficult to verify whether oral notification was in fact given.

<u>EPA Response</u>. EPA considered the comments submitted and remains convinced that increasing workers' awareness of treated areas through additional posting will lead to an overall reduction in occupational pesticide-related illnesses at reasonable cost. Because of the nature of pesticide exposure, the possible latency of effects, and the underreporting of pesticide incidents, it is difficult to find precise estimates of the benefits of the WPS changes. EPA took great care to not underestimate the costs of the WPS changes, and is confident that the estimates in the Economic Analysis are reliable.

EPA disagrees with commenters that assert oral notification alone would provide sufficient notification to workers. As noted in the proposal for this rule (Ref. 2, see reference number 41), research has shown that oral instruction alone may not be an effective method of safety instruction. Because workers face challenges with literacy and understanding English, EPA believes that reducing the reliance on spoken messages and increasing reliance on a clear, graphic, posted warning would better protect workers from the risks of mistakenly entering a treated area before the REI expires. The most recent public data set available from the DOL's NAWS (2011-2012), which shows a majority (69%) of all survey respondents speak Spanish as their primary language and approximately 65% speak little or no English (Ref. 5), supports the need for visual reminders to reinforce oral warnings.

EPA acknowledges that compliance with the posting requirement for outdoor production could require some establishments to change their business practices or monitor posted fields more often. However, the commenter's concern about additional requirements to post "no entry" buffers during application is based on a misunderstanding. The only additional field posting required under this rule is when a product with an REI longer than 48 hours is used in outdoor production. Posting requirements for greenhouses have been reduced.

While EPA recognizes industry improvements in training and supervision, and other efforts to protect workers from improperly entering fields during an REI, these efforts are not required and can vary significantly in quality from employer to employer. In addition, the preamble to the proposed rule cites two studies that support the need for additional field posting (Ref. 2, see references numbered 11 and 60). EPA continues to believe that occupational illnesses related to improper entry into treated fields can be reduced by more robust posting of treated areas.

Enforcement of the Federal WPS is generally the responsibility of state, tribal or territorial pesticide regulatory agencies. EPA will develop compliance monitoring strategies and guidance for the responsible enforcement agencies. In addition, EPA will develop and disseminate guidance for the regulated community on how to interpret and comply with the rule.

EPA considered additional posting requirements presented by farmworker advocacy organizations and was not convinced that the increased cost to employers to post all treated areas, or to post areas treated with products with REIs of 12 hours or greater or 24 hours or greater would result in significantly more protections than the requirement to post areas treated with products with an REI longer than 48 hours. EPA concluded that it is reasonable to expect workers to remember oral warnings regarding REIs for two work days, or about 48 hours total, and to require employers to provide visual reminders for longer periods for the more hazardous pesticides.

B. Revise Content of Warning Sign

1. Current rule and proposal. The existing WPS requires agricultural employers to post warning signs with the words "DANGER," "PELIGRO," "PESTICIDES" and "PESTICIDAS," at the top of the sign, and the words "KEEP OUT" and "NO ENTRE" at the bottom of the sign. A circle containing an upraised hand on the left and a stern face on the right must be near the center of the sign. EPA proposed replacing "KEEP OUT" and "NO ENTRE" with "Entry Restricted" and "Entrada Restringida," and changing the shape containing the face and hand to an octagon (similar to a stop sign).

- 2. Final rule. EPA has decided not to change the text or graphic of the existing warning sign. The final regulatory text for the warning sign content is available at 40 CFR 170.409(b)(2).
 - 3. Comments and responses.

Comments. Two state pesticide regulatory agencies and several grower organizations supported the proposed changes on the grounds that "Entry Restricted" would be less confusing to workers than "KEEP OUT," since entry is allowed under certain circumstances. Many more state regulatory agencies and supporting organizations, grower associations, farmworker advocacy organizations, and public health organizations opposed changing the existing warning sign. Those commenters asserted that "KEEP OUT" sends a much clearer message than "Entry Restricted," particularly to people with lower levels of literacy. They noted that the term "Entrada Restringida" is not common in Spanish, which is the first language of the majority of farmworkers in the U.S., whereas "KEEP OUT" is simple and well understood even by people who do not speak or read English. Commenters pointed to standard readability test results confirming that "KEEP OUT" is easily understood by most six-year-olds, while "Entry Restricted" is placed at the grade 12-13 reading level and would be beyond the reading and comprehension level of the majority of farmworkers in the U.S.

A number of states commented that the existing sign is sufficient. They noted that although "Entry Restricted" is more accurate, it would be a costly change for growers that may lead to confusion and not be more protective than the language on the existing warning sign. States also commented that 20 years of training and experience with the current sign is what makes it effective for keeping workers out of fields under an REI. The state regulatory agencies and farmworker advocacy organizations agreed that for the predominantly low-literacy population of farmworkers, a simpler message, along with training on the message, is more protective than the proposed wording for the warning sign.

EPA Response. EPA was persuaded that the proposed changes to the warning sign would be costly for employers and not increase protections for workers as much as expected. A significant factor in EPA's decision was the additional information presented in public comments regarding the potential lack of understanding of the term "Entrada Restringida." EPA was convinced that eliminating the existing language, "KEEP OUT," in favor of a technically more accurate sign would be less protective for the majority of workers. The goal of the warning sign is to keep workers out of areas that are treated with certain pesticides. Entry into these areas is prohibited while the REI is in effect with a few narrow exceptions. Workers that are directed to enter treated areas under an REI and/or areas where the warning sign is posted must have received pesticide safety training, be provided additional protections, and be informed that their entry is subject to the limitations established for early entry exceptions in the regulation. Because EPA expects that the majority of workers would never enter treated areas during an REI, because 20 years of training and experience have familiarized workers with the message and intent of the sign, and because EPA has added additional training and protection for early-entry workers entering treated areas while an REI is in effect, EPA agrees with commenters that the easily understood message of "KEEP OUT" is most appropriate.

C. Warning Sign Location Revisions

1. Current rule and proposal. Under the existing rule, when signs are required for applications in outdoor production, they "shall be visible from all usual points of worker entry to the treated area, including at least each access road, each border with any labor camp adjacent to the treated area, and each footpath and other walking route that enters the treated area." EPA proposed maintaining the existing posting requirement for outdoor production and clarifying the language to require posting be visible from "each border with any worker housing area within 100 feet of the treated area," rather than "labor camps adjacent to the treated area."

2. Final rule. EPA has finalized the proposed changes to the warning sign location requirements for outdoor production. The final regulatory text for this requirement is available at 40 CFR 170.409(b)(3)(ii).

3. Comments and responses.

<u>Comments.</u> Several state pesticide regulatory agencies, grower organizations, and farmworker advocacy organizations supported the proposal and agreed that it would support EPA's goal of increasing clarity of the rule and enhance the ability of employers to understand their responsibilities under the regulation. Commenters in support of the change noted that "adjacent" is a vague term that may be interpreted differently by different people and that "labor camp" is too limited and does not technically include worker housing. They noted that clearer posting requirements could lead to better compliance and thus be a better system for keeping people living in close proximity to treated fields safe.

Some pesticide manufacturers opposed the proposal on the grounds that it is an overly prescriptive, costly, and unnecessary provision which would not provide additional protection above that already provided by the label and existing WPS.

A public health organization proposed adding pesticide application information and REIs to the posting requirement near worker housing areas. One state regulatory agency suggested revising the language by stating "Each border with any worker housing area provided by this establishment/employer within 100 feet of the treated area."

Several industry associations commented on the timing of the required posting. They noted that requiring signs to be posted prior to but no earlier than 24 hours before the scheduled application could be complicated by inclement weather, equipment malfunctions, or other unforeseen conditions that could delay a planned pesticide application. These commenters requested an exemption be written into the regulation for such delays. Another industry association objected to the requirement that "under no circumstances shall the signs remain posted and uncovered when worker entry is permitted." They contend that employers want to remove signs as soon as possible to allow reentry and the timing provision could lead to technical violations without additional protections.

<u>EPA Response</u>. EPA was not persuaded by the comments that the revised posting location requirement would be a significant additional burden on employers. The requirement only clarifies where employers need to post warning signs but does not increase posting requirements beyond what was intended in the existing regulation. EPA agrees with commenters who noted that increased clarity on posting requirements will lead to better compliance and increase awareness of treated fields by workers who live near treated areas.

EPA acknowledges that scheduled pesticide applications can be delayed by many factors. EPA considered allowing the warning signs to be posted after an application is complete but decided the risk of entry during applications, as well as confusion over when an application is complete, necessitated posting prior to an application. EPA did not establish an exemption that would allow warning signs to be posted more than 24 hours in advance because of the continuing belief that the meaning of warning signs is diminished if they are posted well before the hazard exists. If inclement weather or other factors postpone an application, the regulation does allow the signs to be covered rather than entirely removed.

EPA agrees with the industry association commenter that employers will want to remove warning signs as soon as possible to allow reentry. While the three-day standard for removal remains, the rule also has an exemption for signs to remain posted after the restricted-entry interval has expired as long as certain conditions are met.

VII. Hazard Communication

A. Hazard Information – Location and Accessibility

1. Current rule and proposal. The existing WPS requires employers to display certain information about pesticide applications at a central location on the establishment when workers or handlers are present and an application of a pesticide requiring compliance with the WPS has been made or an REI has been in effect within the past 30 days (referred to as the "central display" requirement).

EPA proposed to replace the existing requirement for the application information to be located at the central display with a requirement for employers to make the application information and additional hazard information accessible upon request by workers, handlers or their authorized representatives.

2. Final rule. EPA has decided not to finalize the proposal. The final rule generally retains the existing requirement related to the location of, and accessibility for workers and handlers to, the pesticide application information, makes some changes to the content of the required information, requires the display of hazard information, and includes the accessibility requirements proposed for workers, handlers, and their designated representatives ("authorized representatives" in the proposal). The employer must display the information at a place on the establishment where workers or handlers are likely to pass by (the "central display"). The information must be displayed when workers or handlers are on the establishment and an application of a WPS-covered pesticide has been made or an REI has been in effect within the past 30 days. After this time, the information must be kept on the establishment for two years and made available to workers, handlers, or their designated representatives or any treating medical personnel. The final rule contains more specificity than the proposal, particularly in reference to the designated representative, where details are drawn from OSHA's rule at 29 CFR 1910 (Ref. 17).

The designated representative must provide written evidence of such designation, including the name of the worker or handler being represented, a description of the specific information being requested, including dates of employment of the employee, the dates for which the records are requested, the type of work conducted by the worker or handler during that period, a statement indicating that the representative is designated by the worker or handler, the specific application and/or hazard information requested, a statement designating the representative to request the information on the worker's or handler's behalf, the date of the designation, and the printed name and contact information for the designated representative. If the information is to be sent to the requester, direction for where that information must be sent is to be included. When the employer is presented a request that contains all of the necessary information specified in the regulations, the employer must provide a copy of, or access to, all of the requested information that is applicable within 15 working days from the receipt of the request. Failure to respond to the request would be a violation of the rule. The final regulatory text for this requirement is available at 40 CFR 170.311(b)(9).

Workers and handlers who worked on the establishment may request, orally or in writing, the pesticide-specific information retained by the employer. The information must have been displayed while the worker or handler worked on the establishment. The employer must provide access to, or a copy of, the information within 15 days of the request. The regulatory text for this requirement is available at 40 CFR 170.311(b)(7).

Under the requirements to provide records to workers, handlers, and designated representatives, EPA also added language similar to that found in OSHA regulations (see 29 CFR 1910.1020(e)(1)(v)) to ensure that whenever a record has been previously provided without cost to a worker, handler, or their designated representative, the agricultural employer may charge reasonable,

non-discriminatory administrative costs (i.e., search and copying expenses but not including overhead expenses) for a request by the worker or handler for additional copies of the same record.

Medical personnel or persons acting under their supervision may also request the pesticide-specific information required to be retained in 170.311(b)(6) to inform diagnosis or treatment of workers or handlers who were employed on the establishment during the time the information was required to be displayed. The request may be provided orally or in writing to the agricultural employer, and the employer must respond promptly to the request. The regulatory text for this requirement is available at 40 CFR 170.311(b)(8).

Lastly, the final rule makes some changes to the content of the required pesticide application information and when it must be posted, as explained in Units VII.C. and VII.D. The final regulatory text for this requirement is available at 40 CFR 170.311(b).

3. Comments and responses.

Comments. The overwhelming majority of commenters requested that EPA keep the existing central display requirement. Many comments from farmworker advocacy organizations, academic institutions, public health organizations, states, unions, a pesticide retailer association, many citizens and some members of Congress noted that they thought it was unreasonable, unrealistic and naïve to think a vulnerable population such as workers and handlers would request hazard information from their employers. These commenters cited many reasons for this position, including barriers (e.g., language differences, concern about compromising their immigration status, intimidation, and fear of retribution, retaliation or job loss) and the power and social dynamics between employer and employee. One state remarked that their experience was workers simply do not want to draw attention to themselves for fear of discrimination. These commenters were adamant that workers and handlers needed ready, anonymous, unhampered access to hazard information as currently provided through the central display requirement. Farmworkers themselves, in letters and surveys, revealed that they would not feel comfortable asking the employer for information. These farmworkers insisted that employers would ignore such a request, reprimand them for halting work, or reply that the information is only for "those spraying," and order them to resume working. One citizen in support of the central display requirement pointed out that no one should assume that farmworkers are aware of the dangers posed by exposure to pesticides or pesticide residues. Many commenters from farmworker advocacy groups, state regulatory agencies and a union noted that one benefit of keeping the requirement is that employers are already mostly complying with it, it is well accepted by the agricultural community, and workers expect to find the information there.

To improve accessibility to information, one state, a public health organization and a farmworker advocacy group suggested requiring that the displayed information include cell phone scan codes linked to pesticide use records and SDSs. A professional organization of trainers and educators suggested setting up an online site for agricultural employers to post and maintain information specific to their operation, thereby making the information available by cell phone and Internet access. However, one state regulatory agency has observed a problem with a system whereby pesticide application information that was called or texted into a recording system was checked once a day, resulting in the posting of incorrect information. Commenters also offered suggestions on nontraditional ways of complying with the central display requirement. For example, one state regulatory agency suggested putting the information in a binder in a work area while a public health organization suggested the use of a hard plastic sleeve to protect the information from weathering. A farmworker advocacy group suggested posting a leaflet at the worksite identifying the location of SDSs and pesticide application records, while another noted that it has seen the information displayed near

bathrooms, hand washing stations and time clocks at nurseries or greenhouses.

State regulatory agencies requested that EPA stratify the central display requirement, but did not elaborate how. One state wanted the display requirement limited to work hours, because of their experience with nighttime vandalism of central displays.

Many commenters supported the inclusion of a designated representative who could request the hazard information on behalf of a worker or handler, as long as the central display requirement was also kept. Farmworker advocacy organizations, public health organizations, unions and citizens cited OSHA's requirements at 29 CFR 1910.1020(e)(1) that require access to exposure records for workers in other industries. Comments in support of including access to hazard information by workers' or handlers' designated representatives note that workers and handlers may be reluctant to request the information for themselves due to their inability to communicate effectively with, or fear of, their employer, or because they may not be able to understand the information without help. Many commenters repeated the need to access information for early diagnosis and treatment. However, commenters also discussed the benefits of having the information in non-emergency situations. Specifically, having the information would allow health care providers to assess risk, educate workers, and offer preventative care to patients who are workers. Along the same lines, two public health organizations thought access would be helpful for incident reporting and differential diagnosis. One farmworker advocacy organization pointed to their need for information so they can knowledgeably respond during pesticide safety training to farmworkers' questions about the health effects of pesticides where they work. One comment described a situation where a farmworker advocacy organization requested such information from an employer on behalf of two ill workers, but their request was denied because the workers themselves did not make the request. One commodity association was in support of a provision for a designated representative. One farmworker advocacy group wanted collective bargaining agents to be able to obtain records as well as designated representatives. A citizen noted that a family of a worker could also need or want access to the information.

In contrast, there was significant opposition from many state regulatory agencies, farm bureaus, the SBA Office of Advocacy and the agricultural industry in general to the proposal for the designated representative, including growers, pesticide manufacturers, and their organizations. Comments from these groups centered on the additional burden on employers to provide the records. Many commenters also expressed concerns that allowing access to pesticide application information by designated representatives could be abused by anti-pesticide organizations and others, who could send people onto the establishment requesting information purportedly on behalf of a worker or handler. One farm bureau described a hypothetical situation, and gave examples of legal challenges to, and alleged harassment of, farmers by persons purporting to be worker advocates. To alleviate this concern, it was suggested by at least one commodity organization and one farm bureau that the designated representative be restricted to someone already associated with the farming operation, such as a foreman.

There was concern expressed by commenters of the privacy of information. Some farm bureaus stated that the requirement for providing the information to a representative is a violation of farmer's legal and privacy rights, stating that the representative could demand all information related to pesticides on that establishment. In one state, a yearlong debate centered around whether or not to keep pesticide application information confidential. Ultimately, the state's solution was to enhance the pesticide use information gathered by the USDA's National Agricultural Statistics Service and still maintain the anonymity of pesticide users.

Some commenters pointed out that the WPS already requires under the "emergency assistance

provisions" that employers provide promptly upon request to workers, handlers or treating medical personnel, information on the pesticide to which a person may have been exposed, treatment information, how the pesticide was used and circumstances of possible exposure. One state regulatory agency suggested that EPA use USDA's provision for making pesticide applicator records of restricted pesticide use available to certified or licensed health care professionals, or those acting under their direction, for the treatment of any individual who may have been exposed to an RUP. The USDA regulation (7 U.S.C. 136i-1) also requires that the information be made available immediately in case of a medical emergency.

One association of state regulatory agencies objected because of the time and administrative burden to themselves and to agricultural employers. Another state regulatory agency was concerned that a requirement to provide information upon request and during normal work hours meant that the agricultural employer would have to be chained to their office in case someone were to appear with a request. According to several grower organizations, unless EPA requires that all records be kept in one physical location agricultural employers may need to respond more than once to a single request since various records could be kept in various places on an establishment. One state was concerned that if the agricultural employer were to make the information available orally or electronically, there would be no record of compliance.

Some state regulatory agencies and other commenters provided recommendations to improve the proposed requirement for a designated representative. Suggested improvements included limiting the designated representative requirement to current workers and handlers or to employees who worked on the establishment within two years of the request, limiting access to medical personnel only, or limiting the request to a specific acute incident. Many state regulatory agencies, a farmworker advocacy organization and others recommended that the request be in written form, on paper or electronically, and include designation of the representative by the worker or handler. One state recommended defining a time frame for provision of the information to the requester. Another state suggested that the request clearly identify the information required to be provided to the designated representative, and the purpose of the request or intended use of the information. State regulatory agencies were concerned about the ambiguity of the requirement to fulfill a request for information no later than the end of the day of the request. A few farmworker advocacy organizations expressed concern that there was no requirement to provide information to the designated representative for free. They maintained that the information should be provided at no cost, as is the case with a similar OSHA requirement.

Many of the commenters in favor of keeping the existing central display requirement explained that a central display requirement that provides information about general pesticide safety, including symptoms of pesticide illness and the specific pesticides used on the establishment, is necessary to protect the health of workers and handlers. First, having information available in non-emergency situations could help workers and handlers be aware of symptoms before they occur, help them avoid exposure, and possibly enhance the reporting of illnesses. Secondly, they stated that emergency medical personnel would not have to lose critical time tracking down information instead of treating the ill or injured person if they could rely on accessing the information quickly from the central display. As expressed by one municipality required to post similar kinds of information, employers' convenience should not outweigh the employees' right to have the information available to them. One farmworker advocacy organization argued that a lack of current information at central displays is attributable to a lack of compliance and not problems with the requirement itself.

EPA also received comments from one pesticide manufacturer organization, a couple of states

and some farm bureaus in favor of the proposal to eliminate the existing requirement for a central display of pesticide application information. These commenters agreed with EPA's observations in the preamble to the proposal that this requirement imposes a paperwork burden and that states often cite employers for technical violations of the display requirement. The commenters stated it is difficult to keep the displayed information current when application plans change, especially on large establishments. They also noted the difficulty keeping information legible when it is displayed at a central location subject to weather conditions. These commenters encouraged EPA to eliminate the existing central display requirement, not to finalize the proposed requirement to provide hazard communication information to workers, handlers, or their designated representative, and to require employers to only keep records of pesticide applications on their establishment.

EPA Response. EPA agrees with those commenters who argued that workers and handlers must have relatively unhindered access to pesticide-specific information, and has decided to retain the central display requirement. Although the extent and type of barriers and employer-employee dynamics are unique to each situation, EPA recognizes that a significant number of workers and handlers face disadvantages that can reasonably be expected to make them hesitant to ask their employers for information relating to their pesticide exposure. As stated by commenters, agricultural employers are accustomed to complying with the requirement and workers and handlers already know to find the information at the central location. EPA recognizes that it is an environmental justice issue and that removing the requirement would be taking a step backwards. Consequently, EPA believes that it is not reasonable to make it more difficult for an employee to obtain this information, particularly given the potential usefulness of the information if an employee may have been harmed by a pesticide. Therefore, EPA has decided to retain the requirement for the pesticide application information to be displayed at a place on the establishment where workers and handlers are likely to pass by or congregate and has added the requirement that the SDS must also be displayed at that location.

In the final rule, workers and handlers, their designated representative and any treating medical personnel may request either a copy of or access to the pesticide-specific information that was required to be displayed while the worker or handler was employed on the establishment. The records of application and SDSs must be retained for two years after the date of expiration of the REI applicable to the pesticide application. Access to the SDSs after the display period will afford workers and handlers information about the pesticides they may have been exposed to, and the hazards they may present.

EPA recognizes, however, that there can be difficulties in complying with the central display requirement. In response to comments about the difficulty of keeping accurate information posted, EPA simplified the central display requirement by changing the required time frame for posting the application-specific information from before the application to within 24 hours of the end of the application. (Unit VII.D.) EPA expects this modification to the requirement for the timing to post the application information will reduce the burden on employers, while providing employees with ready access to accurate information. In response to the comments about the difficulty of maintaining a legible central display when it is subject to weather conditions, EPA notes that the central display requirement does not mandate how or where employers post the information. Rather, the information must be displayed "where workers and handlers are likely to pass by and congregate and where it can be readily seen and read" and workers and handlers must be able to access the information at all times during work hours. This does not preclude the central display from being maintained in a location sheltered from weather conditions, such as a bathroom, break area, or changing area, as long as the requirements of this section are met. Nor does it preclude the information from being displayed in a hard plastic holder or binder. In addition, the requirement for a "central" display does not limit the

employer to only one location on the establishment. If workers and handlers are unlikely to congregate in one place on the establishment, there may be several locations but all of the same information must be present, accessible during work hours and be readily seen and read. Lastly, agricultural employers may provide the information through electronic means (e.g., texts, scan codes, Internet sites), but they must also display paper copies of the application information and SDS since workers and handlers may not have regular, dependable Internet access or cellphone coverage.

EPA has been convinced by comments in support of retaining the option for a designated representative to access hazard information (application information and SDS) on behalf of a worker or handler. EPA agrees that including in the rule a requirement, based on OSHA's rule at 29 CFR 1910.1020, for employers to provide the information to a representative who has been designated to act on the behalf of the worker or handler would give workers and handlers more access to information related to pesticides used in their workplace. Also, EPA is aware that California and Texas regulations include requirements for employee representatives' to be given access to hazard information for farmworkers, and comments from the Texas Department of Agriculture encouraged EPA to require the designation in writing and to limit access to records to the retention timeframe of two years. EPA is unaware of issues related to worker representatives having access to hazard information on behalf of workers in those states. Under this provision, workers and handlers may also request the information directly from the agricultural employer, either orally or in writing.

In response to the many comments opposing the establishment of the authorized or designated representative based on concerns for the potential for anti-chemical activists fraudulently acquiring records, the final rule includes a requirement for the representative to provide to the employer documentation (written authorization) signed by the worker or handler that clearly designates that person to act as his or her designated representative. The information that can be obtained is limited to the application and hazard information that is required by § 170.311(b) of the final rule that was required to be displayed while the worker or handler was on the establishment, and for the dates applicable to the worker's or handler's dates of employment on the establishment. The employer must provide the information regardless of the worker's or handler's employment status on that establishment at the time of the request.

Although the existing WPS requires that agricultural employers provide the pesticide application information under the emergency assistance provision, the difference is that the information can be accessed before an emergency. Medical professionals may request the information if they suspect a chronic exposure, for example. A designated representative may request the information to be able to translate it for a worker, handler or a family member, or, as one commenter emphasized, to be able to knowledgeably answer workers' and handlers' information about exposure during pesticide safety training. These situations would not qualify for access to the information under the emergency assistance provision.

EPA was convinced by comments about the need for the pesticide specific information by medical personnel treating workers or handlers who may have been exposed to pesticides on the establishment, and has added a requirement that employers promptly provide the information to the requesting medical personnel or persons they supervise. The request may be made orally or in writing, but in either case the information that must be provided to medical personnel is the same set that must be provided to an employee or a designated representative. The information would help ensure that the medical considerations would include the possibility that a pesticide exposure was involved in the worker's or handler's illness.

B. Pesticide-Specific Hazard Communication Materials – General

<u>1. Current rule and proposal.</u> The existing WPS requires employers to provide workers and handlers with specific pesticide application information, but not pesticide-specific hazard information, on the pesticides they may be exposed to in the workplace.

EPA proposed to require employers to provide workers and handlers with access to the SDSs and pesticide labeling for products that have been applied on the establishment and to which workers and handlers may be exposed, in addition to the pesticide application information already required to be made available.

2. Final rule. EPA has finalized the requirement for agricultural employers to display at a central location pesticide application information and SDSs for pesticide products used on the establishment (referred to as "pesticide application and hazard information" in the final rule). The same information must be kept as records for two years from end date of the REI, and provided to designated representatives, workers and handlers, and medical personnel upon request. EPA has not finalized the proposal to require employers to provide access to pesticide labeling. The final regulatory text for this requirement is available at 40 CFR 170.311(b).

3. Comments and responses.

Comments on providing safety data sheets and pesticide labeling. EPA received many comments from farmworkers, farmworker advocacy organizations, unions, public health organizations, academics, citizens, a grower organization and a few state regulatory agencies in support of providing information on pesticide-specific health effects to workers and handlers. Most were in favor of providing both the label and SDS. However, many commenters focused their comments on the SDSs because of their information on the health effects of pesticides. It was asserted that migrant clinicians lack farm-specific information for pesticides, and that SDSs would help them make correct and early diagnosis for the treatment of pesticide-related illnesses. One point expressed repeatedly in letters from and surveys of farmworkers, as well as supported by many farmworker advocacy organizations, was the desire of farmworkers to have specific information on what is used, what they are exposed to, and potential effects. Many farmworkers believe that agricultural employers don't care about their health, and insist that employers need to make employee/farmworker health a priority. One farmworker advocacy organization argued the worth of providing the information if it has any possibility of helping workers recognize symptoms of exposure and to seek timely medical care. Research by one academic institution described the positive results of providing pesticide-specific hazard information to farmworkers. First without the information, farmworkers often rely on lay knowledge and sensory perception that can often be dangerous and misleading, such as assuming that no odor means no risk. Second, there is a positive correlation between farmworkers' access and receipt of health and safety information and their safety behavior (e.g., hand washing). Along the same lines, one state regulatory agency supports the belief that well-informed people are able to make better decisions. Furthermore, according to a couple of farmworker advocacy organizations, providing such information would make farmworkers feel more vested in their work and improve employer-employee relations.

On the other hand, a few grower organizations, a farm bureau, a pesticide manufacturer organization and a couple of states were against a requirement to provide labeling and SDSs. These commenters argued that EPA had not made a case strong enough to justify a need. An association of pesticide manufacturers questioned the utility of requiring SDSs when labels or label information can already be requested through the existing emergency assistance provision. At least one grower organization thought it would only create confusion for agricultural employers to obtain and provide SDSs since it is redundant with the OSHA Hazard Communication Standard. One state thought SDSs were too complex and confusing for farmworkers, and using them could result in unintended

consequences. Because of the complexity, employers who are not usually qualified to teach could feel obligated to train workers on the health effects of pesticides. One commodity organization was concerned that the information would be unduly alarming to workers without the proper context. One grower organization said they witnessed workers claiming illness based on the power of suggestion inherent in health effect information, rather than an actual exposure. They fear misdiagnoses since symptoms of a foodborne illness, heat stress and the flu are similar to a pesticide poisoning. They also opposed display of SDSs on the grounds that while the pesticide product label poses legally enforceable requirements on users, SDSs do not.

Some farmworker advocacy organizations, public health organizations, a grower organization, a farm bureau, an academic institution, unions, a state regulatory agency and others thought it would not be much of a burden on agricultural employers to acquire the SDSs of pesticide products because they are easily available online or can be requested from the pesticide manufacturer or distributor. One farmworker advocacy organization gave the Washington State Hazard Communication rule (HC rule) as an example that it is a feasible requirement for employers to make SDSs available to employees. http://www.lni.wa.gov/IPUB/413-012-000.pdf. The Washington State HC rule applies to employers with one or more employees who either handle or are potentially exposed to hazardous chemicals, including pesticides, in their workplace. It requires employers to make SDSs for each chemical that employees may encounter readily accessible and easily obtained without delay during each work shift, and to ensure that employees traveling between workplaces during a work shift can immediately obtain the SDS in an emergency. Several commenters suggested that EPA consider maintaining a repository of SDSs.

In contrast, a couple of grower associations and one state regulatory agency thought it overly burdensome for agricultural employers to obtain SDSs. One state thought it would be difficult for employers to locate the correct SDS for pesticide products. They also noted that small businesses that do not meet the OSHA threshold of 10 employees or more and private applicators would-have the most difficulty since they are not already accustomed to obtaining and keeping SDSs.

EPA received some comments both for and against providing pesticide product labeling. Many farmworker advocacy groups and an association of pesticide manufacturers supported a requirement for the employer to provide the labeling. These commenters maintained that workers and handlers want more information on chemicals to which they may be exposed. One commenter favored providing the label over the SDS because the label is the culmination of regulatory testing and specifies the use of the product so as to mitigate risks to workers, handlers and applicators, and provides environmental safety information for the pesticide and its use on crops.

On the other hand, farm bureaus, growers and grower organizations and states opposed a requirement to provide the labeling. These commenters expressed concern that EPA is expanding its mandate by requiring agricultural employers to provide the product "labeling" when it should be limited only to the WPS portions of the "label." They also were concerned that an agricultural employer could easily violate this requirement by not having the most current or correct version of the labeling, such as a specimen or technical label. They argued that workers and others could look up the label based on application-specific information contained in the pesticide application record.

<u>EPA Response.</u> After consideration of the comments, EPA remains convinced that access to SDSs offers significant health and safety benefits to workers and handlers. SDSs contain information that is not generally included in pesticide labeling regarding chronic, developmental, and reproductive toxicity that can be valuable to exposed and potentially exposed workers, and to medical personnel and others who provide treatment to an ill or injured person. Moreover, given the ubiquity of chemicals subject to

the OSHA Hazard Communication Standard that mandates the development and distribution of SDSs, it is likely that many health care professionals are more familiar with SDSs than pesticide labeling. Requiring the SDS as part of the central display facilitates a quicker identification of the pesticide product used in case of an incident and may assist in diagnosis. The SDS contains information about symptoms expected in a person exposed to the chemical (immediate, delayed and chronic effects) as well as recommended treatment, whereas the label may not include detailed information on symptoms or treatment. EPA recognizes that state pesticide regulatory agencies do not review, approve, or take enforcement action based on the information in SDSs. However, comments from farmworker advocates indicate that workers and handlers want to have more information on health effects, which is available on SDSs and generally not available on the pesticide labeling. OSHA is requiring that all SDSs be in a standard format, making it easier to locate health information (Ref. 17). Accordingly, EPA concludes that a requirement to display and make available SDSs is an effective way to communicate pesticide hazard information important to workers and handlers. EPA notes that under the final rule workers and handlers will learn during pesticide safety training about SDSs, the information they contain, and their availability at central display locations. This addition to the training will further reinforce workers' and handlers' awareness and potential use of SDSs.

EPA is persuaded that access to SDSs is not a significant obstacle to requiring agricultural employers to keep and display SDSs for pesticide products used on the establishment. Agricultural employers can obtain SDSs from the distributor of the pesticide, online, or upon request from the product manufacturer. For example, employers in industries other than agriculture – including retailers and wholesalers of agricultural chemicals - are required by the OSHA Hazard Communication Standard to make available SDSs to their employees.

Upon consideration of the comments, EPA has decided not to require agricultural employers include the pesticide product label or labeling as part of the central display requirement. EPA recognizes the burden on employers to provide both the SDS and label or labeling in addition to the pesticide application information. As noted previously, the SDS contains the health-related information requested in comments by worker advocates, and that would be most useful to persons providing treatment to those who may have been exposed to pesticides. EPA agrees that if necessary, the labeling for a product used for a specific application can be located using the application-specific information that employers are also required to post.

Comments on the extent of the requirement. EPA received comments both to narrow and to expand the scope of the proposal requiring employers to maintain SDSs and make them available to employees. At least one association of pesticide manufacturers, a grower association and a few state regulatory agencies thought the existing hazard communication requirements were sufficient. Among the suggestions to narrow the scope of the proposal, one state and one academic institution wanted EPA to keep a central repository of SDSs for agricultural employers to access. Another suggestion was to require employers to keep the SDS only while the associated pesticide product remains on the establishment. Farmworker advocacy organizations, public health organizations, and one academic institution recommended expanding the proposed requirement to a full Hazard Communication (HC) Standard as required by the Washington State HC for all hazardous chemicals, which requires employers to develop a written Hazard Communication program, maintain availability and access to SDSs, provide information and training on hazards in the workplace, translate certain documents upon request, and keep and provide access to exposure records for at least 30 years. The academic institution explained that employers could be more committed to having a more effective hazard communication program if they had to put in writing. Furthermore, a written program would also serve as verification of

compliance for enforcement staff. One suggestion from a farmworker advocacy organization was to form a safety committee in each workplace to review and provide SDSs and other materials to workers. The safety committee would include farmworkers, thus offering them an opportunity to be leaders at the work site.

Many farmworker advocacy organizations, farmworkers, citizens and one academic institution suggested EPA require that SDSs be available in the workers' native language and provided examples of similar requirements. First, one farmworker advocacy organization cited the Migrant and Seasonal Agricultural Worker Protection Act (29 U.S.C. 1801, et seq.), administered by the DOL, which requires written information on the terms of employment to be provided in English, Spanish or other language common to workers. One farmworker advocacy organization noted that employers are required by the Department of Labor to provide to workers in a language they understand information on wages and working conditions, and that vital health information such as pesticide application records should therefore be treated the same way. Along the same lines, one academic institution explained it is an environmental justice issue not to make the information available in their native language. Furthermore, one state regulatory agency thought it worthless to provide any information only in English.

Many farmworker advocacy organizations, unions, citizens, academics, public health and organizations commenters argued there is a minimal burden to translating SDSs. According to a farmworker advocacy organization, the translation cost would be small compared to the benefits of a more informed workforce and safer workplace. As one union pointed out, the burden to translate SDSs would not be on the farmers, but on pesticide manufacturers who have the resources to do so efficiently. Many gave the Washington state requirement as an example that it is feasible. In Washington state, agricultural employers are required to provide translated documents if requested. Farmworker advocacy organizations asserted that it would be easy to translate SDSs because of the standard format required by OSHA's adoption of the Globally Harmonized System of Classification and Labeling of Chemicals. To address the complexity of information in SDSs, however, one academic institution suggested they be rewritten at the reading level of pesticide handlers. There was also opposition to mandatory translation of SDSs. One pesticide manufacturer organization was against translating the SDS because of cost and the many languages used by agricultural workers.

EPA Response. After reviewing the comments, EPA has decided on an approach that will provide workers and handlers with more information about the potential health effects associated with the pesticides to which they may be exposed without overly burdening agricultural employers. Obtaining the SDSs for products used on the establishment should not be overly burdensome to employers; SDSs are available from pesticide dealers and the Internet. An EPA-managed repository of the SDSs of all WPS pesticides would not significantly improve access and would be a significant burden for EPA because of the number of pesticides used in agriculture. Stakeholders such as grower organizations are free to voluntarily develop SDS repositories with assistance from members. Voluntary programs of this sort would involve limited subsets of all WPS-scope pesticide products and could possibly be accomplished within a short period in comparison to a national, full-scale repository program.

EPA disagrees with commenters' request to adopt a full hazard communication proposal as required by the Washington State HC for all hazardous chemicals. The full set of the WPS requirements in the final rule provide protections similar to those provided to workers in other industries under OSHA's Hazard Communication Standard, while recognizing differences between agriculture and other industries. As discussed in the Agency's 1992 proposed rule on the Worker Protection Standard; Hazard Information (Ref. 18), in response to numerous concerns about potential overlap or conflict between

EPA's July 1988 proposed WPS (Ref. 18) and OSHA's August 1988 proposed Hazard Communications Standard (Ref. 19), EPA committed to work with OSHA to minimize confusion and avoid duplication between the two agencies' requirements. Rather than require agricultural establishments that may not routinely use the same pesticides to develop and maintain a written Hazard Communication Standard plan listing all chemicals that will be used in the workplace, EPA's approach, in both the 1992 proposed rule on Hazard Information (Ref. 20) and this final rule, has been to identify generally applicable requirements, tailored to fit the context of pesticide use in agricultural production that serve a purpose similar to the Hazard Communication Standard requirements in other industries. These requirements include pesticide safety training, display of basic pesticide safety information, notification or posting of treated areas, and access to information about pesticides used in the workplace at a central location. EPA notes that the WPS does not exempt employers with 10 or fewer employees, unlike OSHA's Hazard Communication Standard, and that the cost of a developing and implementing a full hazard communication program specific to each establishment could be burdensome to small agricultural establishments.

Lastly, although EPA is not requiring that SDSs be translated at this time, EPA encourages and supports employers to display this information in such a way that workers and handlers can understand, including translation. EPA is open to conferring with stakeholders on the need for translation and identifying content to be translated, if necessary. EPA notes that some pesticide manufacturers already make pesticide product SDSs available in Spanish and EPA encourages employers to display Spanish SDSs where available and appropriate.

Comments on other forms of hazard communications materials. Many farmworker advocacy organizations, public health organizations, unions, academics, citizens and a couple of state regulatory agencies suggested EPA develop and provide crop sheets, booklets, or other types of materials that describe the health effects of pesticides, either in lieu of or in addition to the SDS. These commenters identified a need for a pictorial booklet that was culturally appropriate and designed for low-literacy audiences on the health effects from exposure to pesticides, based on the information in SDSs. One state suggested that a small booklet with basic pesticide exposure symptoms by classes of chemicals or modes of action, described in layman's terms would be more helpful to workers than SDSs. Many commenters cited a study in Oregon as support for crop sheets, and gave experiences of California and Texas as examples that crop sheets are feasible. The Oregon study claimed to have shown reductions in pesticide exposure of farmworkers who received enhanced pesticide safety training in their native languages. The enhanced training included a crop booklet in the workers' native language with short and long term health effects of pesticides used in the nursery industry. A couple of farmworker advocacy organizations described an increase in interest and engagement by farmworkers when shown sample crop sheets during pesticide safety training.

Commenters gave EPA suggestions. For example, EPA should develop and provide electronic templates for crop sheets, and provide them at training and under PlexiGlas® boxes at field decontamination sites.

Several commenters agreed with EPA's decision not to require crop sheets. One pesticide manufacturer organization and one commodity association opposed the development of crop sheets, mostly because the benefits do not justify the cost.

<u>EPA Response.</u> EPA does not agree with commenters' request to require crop sheets or similar materials because, in EPA's judgment, the benefits of such a requirement would not justify the substantial costs associated with creating, updating, translating and distributing materials for every crop, growing region, and WPS-scope pesticide product. As noted in the proposal for this rule, crop

sheets and other types of material have been developed in the past, with very limited success. For example, one state's crop sheet program proved to be expensive and labor intensive, and the crop sheets were left as litter in the fields, unused.

SDSs already contain information about the potential health effects (acute, delayed, and chronic) associated with use of pesticide products and will be readily available in a uniform format, including provide hazard information in words and in pictograms. Pesticide safety training and the pesticide information display provide workers and handlers with information on the symptoms that may be associated with exposure to the specific pesticides they may have had contact with. If workers or handlers need information about the specific effects of a pesticide with which they have worked, they can consult the SDS.

<u>Comments on inconsistencies in information between labels and SDSs</u>. A pesticide manufacturer organization opposed any requirement by EPA to provide SDSs to worker and handlers upon request. This commenter expressed concern about the confusion that may be caused by inconsistencies between pesticide labels and SDSs. OSHA requires manufacturers to use GHS terms and chemical classification criteria on SDSs whereas EPA does not require their use on pesticide product labels. As a result, SDSs and pesticide product labels could have different hazard statements, pictograms and signal words.

EPA Response. EPA has not finalized the proposed requirement for the employer to make available pesticide product labeling upon request. Instead, the final rule requires the employer to display only pesticide application information and SDSs for pesticide products used on the establishment. The SDS provides succinct information about the known health hazards of the product that typically is not presented as part of the product label or labeling. Such information can be invaluable to medical professionals for the diagnosis and treatment of certain pesticide-related illnesses and injuries. Because EPA is not requiring the employer to display the labeling, EPA does not expect issues with a perception of conflict between labeling and SDSs. The persons who wear PPE and have access to the label are pesticide handlers who receive more thorough training than workers. If pesticide handlers encounter conflicting information on labeling and SDSs, such as the PPE identified, they should know they must follow the instructions on the pesticide labeling, as they are trained to do. For information on OSHA's adoption of the Globally Harmonized System of Classification and Labeling of Chemicals for SDSs and the pesticide product labeling, see EPA's Pesticide Registration (PR) Notice 2012-1, Material Safety Data Sheets as Pesticide Labeling (http://www2.epa.gov/sites/production/files/2014-04/documents/pr2012-1.pdf).

C. Pesticide Application Information – Content of Pesticide Application Information

1. Current rule and proposal. In the existing WPS, the agricultural employer must record and display the following information about each pesticide application: The location and description of the area to be treated, the product name, EPA registration number and active ingredient(s) of the pesticide product, time and date the pesticide is to be applied, and REI for the pesticide.

EPA proposed to require the agricultural employer to record and make available, in addition to the information required in the existing regulation: The specific crop or site treated, the start and end dates and times of the application, and the end date and duration of the REI.

2. Final rule. EPA has finalized the proposed requirements for the contents of pesticide application information, with one change. The final rule requires agricultural employers to record and display the following pesticide application information: Product name, EPA registration number, and active ingredient(s) of the pesticide product applied; the crop or site treated and the location and description of the treated area; the date(s) and times the application started and ended; and the duration of the REI. The final rule does not require the employer to record the end date of the REI. The

final regulatory text for this requirement is available at 40 CFR 170.311(b)(1)(ii)-(v).

The agricultural employer must record and display the information about the crop or site treated and the location of the treated area. EPA encourages employers to display the information in such a way that workers and handlers can understand and distinguish each treated area from all other areas on the establishment; in some cases, a map or diagram may be appropriate.

EPA encourages and supports the display of application information so it is most useful to workers and handlers on the establishment. One such option is to separate the information about treated areas, so those areas where an REI is in effect are distinct from those where the REI has expired, allowing the viewer to more quickly identify areas where entry is restricted. Similarly, maps highlighting areas where an REI is in effect and those where the REI has expired could also present the information in a user friendly, pictorial manner. EPA also sees an opportunity for employers to provide information of this nature through texting and other electronic means to their employees, and encourages such communication, in addition to the requirement for maintaining this information as part of the central display.

3. Comments and responses.

Comments. Many farmworker advocacy organizations, a few state regulatory agencies, a farm bureau, an academic institution, a grower organization, a union and others supported the proposed expansion of the content requirement for pesticide application information records. According to these commenters, it would be a small burden to require additional application information, such as crops treated, that could help workers proactively avoid exposure to pesticides. Many farmworker advocacy organizations insisted that the additional information would have been helpful to state regulatory agency investigations and for the ability of workers and their families to keep themselves safe. A few state regulatory agencies agreed that the additional information is essential for enforcement, and one remarked that their state already required this information. According to a public health organization, the agricultural employer already has the information so there would be no additional burden. The information would assist workers in proactively avoiding exposure as well as health care providers when evaluating and determining treatment for non-emergency exposure. One state regulatory agency asked EPA to parallel the information required by USDA to avoid confusion for the applicator, agricultural employer and state enforcement personnel, while another suggested that more information be required in addition to the information proposed to assist state pesticide regulatory personnel in determining compliance. Along the same lines, a union wanted EPA to add all of the ingredients and the Chemical Access Service registry number to the records. Lastly, many commenters including citizens, farmworker advocacy organizations and unions also wanted the pesticide application information written, and/or orally communicated, to workers in their native language. A few states, two farmworker advocacy organizations and other commenters suggested various combinations of records limited to three or fewer pieces of information.

Several farm bureaus, a pesticide retail association, one grower organization and several states opposed any changes. These commenters asserted that the content required by the existing regulation is already too burdensome and amply fulfills the need. Many of these same commenters opposed EPA's proposed expansion of the content of records stating that EPA had not justified it with quantifiable benefits. These commenters suggested that EPA's expansion of content was merely for additional enforcement actions, with little to no benefit to the health and safety of workers. Furthermore, another grower organization pointed out that workers will receive oral and posted notification before entering a treated area. One grower organization argued that only a record of the active ingredient is needed for medical treatment. Lastly, these commenters maintained that recordkeeping of general use pesticide

applications is not required by law, the proposed requirement is duplicative of state and federal requirements, and commercial applicators already keep records.

EPA Response. EPA agrees with the comments that adding more information to application records is a small burden compared to the benefits of determining compliance and giving workers and handlers information to verify the location of treated areas. The crop or site treated, start and end times and date(s) of the application, and duration of the REI are important for protecting worker and handlers and useful for determining compliance, for health care provider evaluations and treatment options, and for workers and handlers to take preventative protection against exposure. Although workers and handlers will see warning signs and/or be notified orally of treated areas, the application-specific information will not be available to them under those specific provisions. The final rule requires that certain application-specific information for the treated area for which the workers will be conducting early-entry tasks must be communicated orally to early-entry workers in a manner they can understand. Workers and handlers will be able to see the application information at the central display while the REI is in effect and for 30 days thereafter (or until workers and handlers are no longer on the establishment, if that is less than 30 days), and by requesting a copy during the two year recordkeeping period. Being able to see and review the information allows for a better informed workforce which, in conjunction with the other provisions, helps workers and handlers take preventative measures against exposure. Workers and handlers who know what they have been exposed to and when, and are aware of the potential symptoms and treatment, are more likely to recognize when they need medical care, and are better equipped to provide their relevant histories to health care providers who have to choose a treatment option.

Agricultural employers, compliance officers, workers, handlers and others will be able to calculate the end date and time of the REI by having the end date and time of the application and the duration of the REI included in the pesticide application information. The combined information will also help workers and handlers identify the areas where an REI is in effect. EPA did not propose requiring more information because the proposed content of application records fits the needs of stakeholders to determine compliance and to give workers and handlers the ability to discern which area had been treated. An arbitrary limit of only three or fewer pieces of information may not achieve the same benefits.

EPA is not requiring agricultural employers to translate or interpret the pesticide application information into the native language of workers. Although the translated information would provide significant benefits, the burden of translation would be significantly higher than providing the information in English, and it is not clear that the benefits would be so much greater than the requirement to provide the information in English. EPA anticipates that the new requirement allowing designated representatives access to the application-specific information will help convey that information to workers and handlers who do not understand English. Also, it appears that some SDSs are already being provided in Spanish, and perhaps other languages, as well as English, which may benefit many employees. Lastly, the lack of a requirement does not preclude voluntary translations and interpretations by farmworker advocacy organizations or agricultural employers.

The WPS requires agricultural employers to maintain records because those records provide information that is important for the protection of their employees. While a significant number of agricultural employers may also be certified as private pesticide applicators, their status as private applicators does not exempt them from the WPS recordkeeping required of agricultural employers. The WPS does not require private applicators to maintain records on account of their status as private applicators.

The risks of concern under the WPS include both RUPs and non-RUPs, while certification requirements at the federal level, including recordkeeping, only apply to those using RUPs. Neither the USDA application record requirements for private applicators of RUPs, nor state application record requirements for commercial applicators fully cover the information needed under the WPS for the protection of workers and handlers. The USDA required information does not include the active ingredients, duration of the REI or the start and end dates and times of applications, nor does it apply to applications of non-RUP pesticides. Commercial applicators would have to record the information required by the state pesticide regulatory agency, which must at a minimum include the kinds, amounts, uses, dates and places of RUP applications. 40 CFR 171.7(b)(1)(iii)(E). Also, state pesticide regulatory agencies may or may not require records of non-RUP applications. Therefore, it is unlikely that all states' commercial applicator RUP application records will match exactly the record requirements of the WPS. Because the records required to be maintained by USDA and the states do not include all of the information needed for protection of workers and handlers, it is appropriate to require such recordkeeping through the WPS.

D. Pesticide Application and Hazard Information –When Information Must Be Made Available

1. Current rule and proposal. In the existing rule, the agricultural employer must record and display the pesticide application information before the application takes place, if workers or handlers are present on the establishment before the application begins. Otherwise, the information must be recorded and displayed at the beginning of any worker's or handler's first work period. If the employer posts warning signs for a treated area, the pesticide application information must be displayed at the same time as, or earlier than, the warning signs. The information must remain on display when workers are on the establishment and from the time of the application until 30 days after the REI expires or until 30 days after the application end date if the REI is 0 hours (or in the rare instance where a label might not have an REI).

EPA proposed to eliminate the central display requirement and require the agricultural employer to provide the pesticide application information, the SDS and labeling upon request from a worker, handler or authorized (now "designated") representative during normal work hours, no later than the end of the day.

2. Final rule. The final rule keeps the central display requirement and requires the agricultural employer to display the pesticide application information and the SDS (pesticide application and hazard information) at the central display no later than 24 hours after the application is complete. Also, the employer must display the pesticide application and hazard information for a treated area before any worker is permitted to enter that treated area, and for thirty days after the REI has expired. If workers will be in the area, they must be notified of the application before it starts, by posted signs or orally, and warned not to enter the area. The application information and SDS must remain posted for 30 days from the expiration date of the REI or from the application end date if the REI is 0 hours (or in the rare instance where a label might not have an REI). EPA did not finalize the proposed requirement for the agricultural employer to make available the pesticide application information and SDS no later than the end of the day of the application. Instead, the agricultural employer must provide the pesticide application information and hazard information within 15 days of a written or oral request from a worker or handler, or a written request from a designated representative. This new requirement is in addition to the requirement to make exposure information promptly available to treating medical personnel. The final rule eliminates the existing requirement to display the application information before or at the same time a warning sign is posted at a treated area. The final regulatory text for this requirement is available at 40 CFR 170.311(b)(5) and 40 CFR 170.309(l).

3. Comments and responses.

Comments. Many farmworker advocacy organizations, citizens, a state regulatory agency and public health organizations requested that EPA keep the existing requirement to make information available before the application so workers and handlers would be able to connect symptoms to an application if the exposure occurred during the application. While many farmworker advocacy groups supported the display of information before an application, some expressed concern about the accuracy of the pesticide application information displayed when the application changed from what was planned and the displayed information was not updated.

On the other hand, many comments from a pesticide manufacturer association, several farm bureaus, and many state regulatory agencies, commodity organizations and applicator organizations requested more time for the agricultural employer to post the information at the central display. They also requested an enforceable time period for posting the information and providing it to designated representatives, workers, and handlers. Several farm bureaus, an academic institution, and one pesticide manufacturer organization requested that EPA require employers to make the information available after the application. An academic institution noted that it is difficult for agricultural employers, who often hire commercial applicators, to get the information by the end of the day. Several farm bureaus, many commodity organizations and a pesticide applicator association wrote about the complications of providing accurate and timely information when application plans are changed because of the weather, the unexpected presence of people in the area, or other unforeseen events. Along with multiple fields at any one establishment and multiple customers over many establishments, these changes make it difficult for applicators to keep agricultural employers informed of up to date information. According to a commodity organization and a grower, sometimes records are not complete until the following day, or need to be verified and corrected. Also, more time helps with scheduling other field activities around pesticide applications and avoids confusion when posting multiple schedule changes. Several commodity organizations pointed out that there are applications that take place at night and overnight, making it difficult to decide what "the end of the work day" was, particularly when nobody is present for applications such as smoke or automatic fog.

<u>EPA Response</u>. EPA agrees with the commenters that it is important to provide workers and handlers with accurate information about pesticide applications. Displaying the information after the application is completed benefits workers and handlers because they can be confident the information is correct, and the employer no longer has to change the information when application plans change. Under the final rule, EPA expects all displays of pesticide application information will contain accurate information. The final rule retains the requirement for workers to receive oral notification, or to see posted warning signs, or both before an application begins, informing them to stay out of an area before an application begins. Also, the final rule assists with compliance and enforcement by giving specific time periods for displaying information at the central location and providing information at the request of workers, handlers or designated representatives.

- E. Pesticide Application and Hazard Information Retention of Records
- 1. Current rule and proposal. The existing WPS requires employers to maintain pesticide application information at the central display from the time of application until 30 days after the REI expires. There is no requirement for the employer to retain the pesticide application information in any form after that time.

EPA proposed to require employers to retain, for each application of a WPS-covered pesticide, the pesticide application information, labeling and SDS, for two years from the date of the end of the REI for each product applied.

2. Final rule. The final rule requires agricultural employers to retain the pesticide application information and the SDS for the product used (pesticide application and hazard information) for two years from the date of expiration of the REI applicable to the application conducted. EPA has not included the proposed requirement for the employer to retain the pesticide labeling in the final rule. The final regulatory text for this requirement is available at 40 CFR 170.311(b)(6).

3. Comments and responses.

Comments - timing. EPA received many comments supporting a two-year recordkeeping requirement from some state pesticide regulatory agencies, several grower organizations, a few academic institutions, and a pesticide safety educator association. One of the grower associations supported EPA's assertion that two years was sufficient for employees to access records and states to investigate complaints. An academic institution supported a two-year recordkeeping requirement, stating it would improve the state's ability to follow-up on referrals it makes on reported cases of pesticide exposure. One state pesticide regulatory agency commented that it did not have a need for the information after one year, but that two years was not much more of a burden. A state regulatory agency and a grower organization commented that the records should be kept for two years from the date of application, rather than from when the REI expires. Many commenters requested EPA to require records to be kept for longer than two years. There was support by an agricultural association and an applicator for a four-year recordkeeping period if the minimum age requirement for early entry workers and handlers was 16 years old. The commenters reasoned that a four-year requirement would mean that records would remain available for two years after they turned 18 years old, in the event of a lawsuit One academic institution and a farmworker advocate endorsed a five-year requirement to coincide with the statute of limitations for civil violations as was suggested by EPA. Several farmworker advocates supported keeping records for seven years, because illnesses may take longer than two years to develop. These commenters also claimed that seven years was feasible because it is a requirement in Washington. An academic association and many farmworker advocates supported a recordkeeping period of at least 30 years, which is consistent with OSHA's requirement, in order to help with the diagnosis of chronic health effects that could be related to pesticide exposure.

Many commenters, including farm bureaus, grower associations, the SBA Office of Advocacy, a few state pesticide regulatory agencies, a pesticide manufacturer and several agricultural organizations opposed a two-year recordkeeping requirement. Some commenters opposed any recordkeeping because they asserted that EPA could not show quantifiable benefits. These commenters argued it would be a paperwork exercise without health and safety benefits driven based on the needs of enforcement. Some other commenters shared these concerns and said that the proposed approach should be replaced with a minimal, non-intrusive requirement such as a one-year time period. One commenter suggested requiring employers to keep records only during the harvest season (crop year). A grower organization argued that last year's records have no bearing on worker protection in real time. Several grower associations thought two years did not make sense, partly because the plants would no longer be there. A state regulatory agency recommended limiting recordkeeping to only when the pesticide product is on the establishment, either in use or available for use. One agricultural association was concerned that an increase in documentation and recordkeeping would force state regulatory agencies to divert scarce resources from compliance and enforcement to the auditing of records.

<u>EPA Response</u>. EPA has concluded that a two-year record-keeping requirement would be helpful for health diagnoses and investigation purposes. EPA considered requiring the retention of records for five years and asked state pesticide regulatory agencies about their needs for access to pesticide application records. These enforcement agencies informed EPA that they rarely need to rely on records

beyond the two-year timeframe. EPA agrees with the commenters who pointed out that two years allows a reasonable amount of time for follow up by state inspectors because it can take some time for incidents or cases of potential pesticide exposures to come to the attention of state pesticide regulatory agencies. In addition, a two year time frame allows time for workers and handlers to obtain the information if they develop an illness, which they may not associate with pesticide exposure when symptoms first develop. EPA decided not to extend the recordkeeping period longer than two years to find a balance between having the records available for a reasonable amount of time and minimizing the burden on agricultural employers.

Comments – format of records. A grower organization asserted that agricultural employers generally keep two sets of records: one at the central location and one on file, and therefore would need to keep both updated. Some commenters, including state pesticide regulatory agencies, applicator organizations and a farm bureau urged EPA to allow records to be kept electronically to facilitate compliance and minimize costs. The SBA Office of Advocacy commented that it would be difficult and time-consuming for small businesses to obtain, print and file SDSs and labeling. They acknowledged, however, that if EPA allowed electronic recordkeeping it would help alleviate the burden. A farm bureau stated that keeping all SDSs and labeling on hand in paper form for two years could take a lot of storage space and would be difficult to keep up to date, because labels are updated often and sometimes products are discontinued.

EPA Response – format of records. EPA notes that this recordkeeping requirement does not necessarily impose a duplicative burden on agricultural employers to obtain pesticide application information and SDSs twice – once to satisfy the central display requirement and once to satisfy the recordkeeping requirement. Agricultural employers may satisfy this recordkeeping requirement by the removal of the pesticide application information and SDS from the central display 31 days from the expiration of the REI (or from the end of the pesticide application if there is no REI) and retaining those records for two years from the date of application. EPA recognizes that some employers may choose to maintain electronic copies of pesticide application records and the product SDS to satisfy both the central display and recordkeeping requirements. The WPS does not specify that records must be kept on paper, so an employer can maintain records electronically as long as the employer satisfies all related requirements of the WPS for both provisions, including keeping the pesticide application and hazard information display accessible to workers and handlers, and being able to quickly access and provide the required materials in the event of a pesticide emergency.

VIII. Information Exchange Between Handler and Agricultural Employers

- 1. Current rule and proposal. The existing WPS requires handler and agricultural employers to exchange information about pesticide applications. When handlers are employed by an employer other than the agricultural employer, the existing WPS requires the agricultural employer to provide the handler employer with information about treated areas on the agricultural establishment the handler may be in (or may walk within one-quarter mile of), including specific location and description of any such areas and restrictions on entering those areas. The existing WPS requires handler employers to provide agricultural employers with the following information prior to making a pesticide application on the agricultural establishment:
 - Location and description of the area to be treated.
 - Time and date of application.

- Product name, active ingredient(s), and EPA registration number for the product.
- REI for pesticide(s) applied.
- Whether posted notification, oral notification, or both are required.

• Any other product-specific requirements on the product labeling concerning protection of workers or other persons during or after application.

The agricultural employer must display information about the applications for workers and handlers employed by the establishment at the central location. The existing WPS requires handler employers to inform agricultural employers before the application takes place if there will be changes to scheduled pesticide applications, such as changes to scheduled pesticide application times, locations, and subsequent REIs.

In addition to maintaining the current requirements, EPA proposed to require the agricultural employer to also provide to the handler employer information about the location of "entry-restricted areas" on the establishment. EPA also proposed to require the handler employer to communicate to the agricultural employer the start and end times of pesticide applications and the end date of the REI. EPA also proposed to relax existing WPS requirements by requiring handler employers to provide information about any changes to pesticide application plans to the agricultural employer within two hours of the end of the application rather than before the application. Changes to the estimated application end time of less than one hour would not require notification.

Finally, in the proposal, EPA unintentionally omitted the provision in the existing WPS that the agricultural employer need not provide information to the handler employer about treated areas if the handler will not be in or walk within one-quarter mile of those treated areas.

2. Final Rule. Information exchange from agricultural employer to handler employer. The final rule requires the agricultural employer to notify the handler employer of any treated areas where an REI is in effect and any restrictions on entering those areas. EPA has not included in the final rule a requirement for the agricultural employer to communicate to the handler employer information about the location of "entry-restricted areas" on the establishment because of the changes to the requirement concerning entry-restricted areas, as discussed in Unit IX.B. EPA has also revised the final rule to correct the unintentional omission of the existing rule's exception that the agricultural employer need not provide information to the commercial handler employer about treated areas if the handler will not be in, or walk within one-quarter mile of those areas. The final regulatory text for these requirements is available at 40 CFR 170.309(k).

Information exchange from handler employer to agricultural employer. EPA has finalized the proposal to expand and clarify the information the pesticide handler employer must provide to the agricultural employer with minor modifications. The final rule does not require the handler employer to convey the end date of the REI to the agricultural employer. The final regulatory text for these requirements is available at 40 CFR 170.313(i).

Timing of exchange of information from handler employer to agricultural employer. EPA has modified the final rule to specify two situations where the handler employer must notify the agricultural employer of changes to the application information before the application takes place. Changes to the date(s) and start and estimated end times of application or to the product name, EPA registration number, and active ingredient(s), must be communicated to the agricultural employer prior to the application. Updates to any of the other information handler employers are required to exchange must be provided to the agricultural employer within two hours after completing the application. The final regulatory text for these requirements is available at 40 CFR 170.313(j).

3. Comments and responses.

<u>Comments</u>. Many states and a few farmworker advocacy organizations expressed general support for the proposal to expand the information to be exchanged. These commenters agreed the additional information would help agricultural employers protect workers, and reduce pesticide-related

illnesses and exposure from drift during applications. Many farm bureaus, states, applicators and applicator associations and an agricultural organization generally disagreed with the proposed expansion. Some of these commenters argued that the proposed requirements are unrealistic and impractical given the dynamics and unpredictable factors involved in a farming operation, such as pest infestations and weather changes. In addition, they argued that the proposal would require multiple parties to exchange information, resulting in the potential for miscommunication. Some commenters also opposed the proposed expansion of information exchange because EPA did not provide documented justification. Crop consultants, an applicator association and a farm bureau indicated the proposal is unnecessary because close coordination of information already exists between applicators, handlers, crop consultants, and growers. Furthermore, they stated that not only are handlers already required to keep workers out of areas during applications, applications are often scheduled to take place when workers are absent. A few states, farm bureaus and a crop consultant opposed EPA's proposal to add to the information the agricultural employer is required to give the handler employer. One crop consultant indicated the information is already on purchase orders or sales agreements between growers and commercial handlers or their employers. One state requested that EPA omit the application start time because it is not used to calculate the REI.

EPA's proposal on the timing to provide notice of a change in application plans elicited many comments. Many commenters indicated that requiring handler employers to provide information about any changes to pesticide application plans to the agricultural employer within two hours of the end of the application would be impractical or impossible, and said that such a change would be an unreasonable burden. One state and several farmworker advocacy organizations endorsed the requirement because of the ease of providing the information in the timeframe by relying on existing electronic capabilities. One farmworker advocacy organization urged EPA to require that changes be communicated before the start of the application in order to enable employers to be able to keep workers out of the treated area.

To prevent confusion about scheduled and actual start and end times and to avoid miscommunication, one state suggested that EPA require the handler employer to inform the agricultural employer of changes at any time on the application day. Two aerial applicators explained that a two-hour window for notification of change sounds reasonable on paper, but not in practice. During long workdays of the busy season, applicators would have to make phone calls in the middle of the night and send text messages, usually from the airplane during or in between applications. Also, it can take more than one day to complete an application because of factors such as the weather, a change in wind direction, or verifying the presence of bystanders. These situations could require the handler to give several updates to multiple parties, resulting in a greater chance for errors and noncompliance.

One commenter requested that EPA require notification of a change within 24 hours from the end of the actual application, while another advised EPA to require notification if the actual application completion time is two or more hours later than the scheduled application time. Several farm bureaus, a pesticide applicator and a crop consultant organization advised EPA to require that changes in application plans be communicated: Before the scheduled date and times, if the application is going to be made earlier than expected, or before the end of the REI as scheduled, if the application is made later than expected. One aerial applicator stated that if an REI is greater than 24 hours, EPA should require an information update before the scheduled REI expires or within 24 hours of the scheduled application time. Another aerial applicator recommended the handler employer and handler give the agricultural employer a window of estimated start and completion date(s) and time(s). In this situation, the handler

would not make the application outside of that window without the approval of the agricultural employer, who in turn must keep workers out of the area during that time, unless notified of a change in the application start and completion date(s) and time(s).

Many commenters noted the absence of the existing provision that the agricultural employer need not provide information to the commercial handler employer if the handler will not be in or walk within one-quarter mile of an area that may be treated with a pesticide or under an REI, and noted this could result in the need to provide excessive, unnecessary information.

<u>EPA Response.</u> The information exchange requirements ensure that agricultural employers and handler employers have the information they need to comply with the requirements for notifying workers and handlers of risks associated with pesticide applications and treated areas (i.e., agricultural employers are required to notify workers of treated areas and display pesticide application and hazard information at the central location on the establishment for workers and handlers to see, and handler employers must inform their handler employees of treated areas on the agricultural establishment near where they work).

EPA has been convinced not to adopt the proposed change to expand the information required to be communicated by the agricultural employer to the handler employer to include information about the location of "entry-restricted areas" on the establishment. Requiring employers to exchange this information would not be practical given other changes in the rule related to the "entry-restricted areas" (replaced by "application exclusion zones" in the final rule) that make the tracking of such areas infeasible. EPA also agrees that it is not necessary for the handler employer to calculate the end time of the REI for each application and include it in the information conveyed to the agricultural employer. The requirement to provide this piece of information has been deleted from the final rule.

Most of the other information required to be exchanged by the final rule is already required to be exchanged by the existing rule, and therefore EPA does not agree that this requirement presents a substantially increased or unreasonable burden. Agricultural and handler employers are currently required to exchange information so agricultural employers may provide notification of application and treated areas under an REI to workers and handlers. Without this information transfer, accurate and timely notification would be difficult to achieve, exposing workers and handlers to potential exposure to pesticides. It is critical that the agricultural employer know the start times of applications in order to be able to notify workers and handlers (when they are on the establishment) so they may avoid treated areas. EPA recognizes that exchange of the expanded information may already occur on some establishments and expects those entities to experience less burden than in situations where such coordination has not already developed.

EPA recognizes that much of the information required may be available on sales agreements and purchase orders between commercial pesticide handlers and agricultural employers, which will reduce the burden for employers to gather it; however, without inclusion of the information exchange requirements in the WPS there is no assurance of timely exchange of all of the necessary information.

EPA considered the range of options suggested for the timing of the information exchange. EPA found it confusing that many commenters indicated that the proposal requiring handler employers to provide information about any changes to pesticide application plans to the agricultural employer within two hours of the end of the application would be impractical or impossible, because the proposal was actually granting a relaxation of the existing requirements that the handler employer must provide complete and accurate the information to the agricultural employer before the application takes place in all cases. The burden of providing updated information within two hours after the application is

significantly less than the burden of assuring that the application will be completed without change as originally communicated.

That so many commenters did not acknowledge that the proposal was granting a relaxation of the current requirements for some situations indicates widespread misunderstanding of the current rule's requirements. Therefore, EPA will focus its outreach efforts during rule implementation to ensure that the regulated community is aware of the rule's requirements in this area, and that they understand the importance of the information exchange requirement in protecting workers and handlers.

However, the comments convinced EPA that the proposed changes regarding information exchanges between the handler and agricultural employer are important and necessary to accommodate the unique situations involved in agricultural pesticide applications and to provide the needed flexibility for the information exchange between the handler and agricultural employers. Several of the recommendations for notification of application changes from the commercial pesticide handler employer to the agricultural employer can be accommodated under the final rule. For example, the applicator and agricultural employer can agree on a window of the estimated start and end times, with the understanding that the application would be made during that period, unless the two communicate and agree to a different timeframe. This would allow the agricultural employer to notify workers of the treatment, keep them from the area, and create and post the application information, satisfying the requirement.

EPA did not identify any suggestions from commenters apart from those that would be covered by the final rule that would meet the needs for agricultural employers to provide employees notification of the application and inform them of treated areas under an REI, and to record and display the pesticide application information. Agricultural employers must have information about the start time of the application before it begins to ensure they have the ability to notify workers of the application before it commences. Agricultural employers must have the end time of the application to notify workers that although the application has ended, entry to the treated area remains prohibited because an REI is in effect. Without these details being provided prior to the application, agricultural employers are not able to fulfill their responsibilities to protect workers. Therefore, EPA has retained the provision of the existing WPS that requires the handler employer to notify the agricultural employer of changes to the application information regarding timing and the product applied before the application takes place. In regard to changes other than timing and the product applied, EPA has adopted the proposal to allow the handler employer to provide updated information to the agricultural employer within two hours after completing the application. The final regulatory text for this requirement is available at 40 CFR 170.313(i).

EPA notes that the method for notification of changes to application information should be agreed upon between the handler employer and the agricultural employer to ensure receipt, and can be accomplished through electronic media, telephone, or other means. The agricultural employer must receive the information in sufficient time to record and display the information for workers and handlers.

Finally, EPA acknowledges that many commenters noted that the proposal omitted the provision at § 170.120(b)(3)(i) of the existing WPS that said that the agricultural employer need not provide information to the handler employer about treated areas on the establishment if the handler will not be in or walk within one-quarter mile of those treated areas. EPA acknowledges this was an inadvertent omission, and therefore EPA has included that provision in the final rule.

IX. Drift-Related Requirements

The requirements discussed in this section are intended to decrease the number of incidents in

which workers and other persons are exposed to pesticides through unintentional contact during application. Drift is the off-site movement through the air of pesticide droplets or particles originating from pesticides applied as liquids or dry materials. Workers errantly in the area being treated may be directly exposed to pesticides during application. In addition, bystanders (both workers and nonworkers) located outside a treated area may be exposed when pesticide droplets or particles move outside the area being treated through the air during and/or immediately after the pesticide application. As used here, the term "drift" includes both of these modes of exposure, but does not include off-site movement of pesticide-imbedded soil-borne particles by wind or vapor drift through volatilization of applied pesticide, although these are often categorized as "drift" in other contexts. EPA has developed methodologies for assessing the risks to bystanders from exposure to pesticides from drift and also from volatilization, and addresses risks of concern and other issues via the registration review process. The purpose of the requirements discussed in this section is to prevent workers and other persons from being exposed to pesticides by unintentional contact during application. The term "drift" is used as shorthand in this section to refer to unintentional exposure from both direct exposures to workers in the area being treated and drift exposures to workers and bystanders.

A. Overarching Performance Standard

1. Current rule and proposal. The existing WPS includes two related requirements that prohibit a pesticide from being applied in a way that contacts workers or other persons. Agricultural products subject to the WPS must have this statement on the label: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." 40 CFR 156.206(a). Also, the existing WPS requires the handler employer and the handler to assure that no pesticide is applied so as to contact, either directly or through drift, any worker or other person, other than an appropriately trained and equipped handler. These requirements prohibit application in a way that contacts workers or other persons both on and off the agricultural establishment where the pesticide is being applied.

EPA did not propose any changes to the label statement. EPA proposed several minor wording changes to the WPS requirement for the handler employer and the handler, but the impact of the proposed requirement would be the same as under the existing WPS.

2. Final rule. EPA has finalized the proposed changes to the requirement for the handler employer and handler with a minor change. The final rule changes the language from the proposed "handler located on the establishment" to "handler involved in the application." As with the existing rule, the final rule prohibits contact to workers and other persons regardless of whether or not they are on the agricultural establishment. The final regulatory text for this requirement is available at 40 CFR 170.505(a). There are no changes to the label statement at 40 CFR 156.206(a).

3. Comments and responses.

<u>Comments.</u> Many commenters, including states and their organizations, grower associations, farm bureaus, pesticide applicators and their organizations and pesticide manufacturer associations, stated that the existing two requirements adequately protect workers and bystanders from exposure during applications. These commenters opposed the other drift-related requirements that EPA proposed (entry-restricted areas for farms and forests and the requirement to suspend applications under certain conditions) as unnecessary, asserting the proposed requirements do not provide any additional protection.

Many respondents from states and their organizations, grower associations, farm bureaus, pesticide applicators and their organizations and pesticide manufacturer associations commented that EPA's risk assessments and pesticide labels include conservative protections for applicators, handlers,

workers and bystanders. Some of these commenters argued that the existing restrictions on the labels, including REIs and pesticide-specific buffers, provide sufficient protection to workers and bystanders.

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A farm bureau commented that the potential for drift is affected by many situational factors, so it is better to rely on applicator training programs, state regulation of localized drift problems and pesticide-specific label statements where appropriate.

Many commenters, including farmworker advocacy organizations and a university, stated that EPA should require agricultural employers to inform their neighbors when they are going to make a pesticide application so workers and others can stay out of the area during the application.

Many respondents from all commenter types commented on incidents where workers or bystanders reported being contacted by pesticides that were being applied. Some of these incidents involve workers in the areas where pesticides were applied and other incidents involve workers or bystanders being exposed to pesticides that drifted off the target site. Many of the commenters cited three broad studies that looked at data from SENSOR-Pesticides and California's Pesticide Illness Surveillance Program (Refs. 10, 11 and 12). A grower organization pointed out that the study of drift incidents from 11 states (Ref. 12) found that, of the drift events with information on violations of pesticide regulations, a majority had one or more FIFRA violations that may have contributed to the drift exposure and suggested that better adherence to and enforcement of existing regulatory requirements could decrease the number of drift exposures. The study found that applicator carelessness contributed to almost half of the events where contributing factors were identified and noted that "applicators should be alert and careful, especially when close to non-target areas such as adjacent fields, houses, and roads" and that applicators "should use all available drift management measures and equipment to reduce drift exposure." Other commenters, including farmworkers, farmworker advocates, public health organizations, a university and a state department of health, cited specific incidents of exposure from drift to workers in the area being treated, or by being sprayed directly. Some applicator, retailer and pesticide manufacturer associations cited state data showing that there has been a decrease in drift complaints over time, dropping from an average of 333 complaints per year nationwide (from 1996 through 1998) to an average of 247 complaints per year (from 2002 through 2004). Some grower and pesticide manufacturer associations cited an analysis by one of these commenters of incidents in California in one year, which showed that there were over 2.4 million pesticide applications and 76 cases of worker exposure to drift. These commenters claimed that none of the 76 cases of drift would have been prevented by implementing the proposed entry-restricted areas.

EPA Response. EPA disagrees with the assertion that the "do not contact" requirements, along with the other protections on pesticide labels, are by themselves sufficient to protect workers and bystanders from being directly contacted by pesticides that are applied. First, many commenters cited incidents where people were directly exposed to pesticide applications, even if there was disagreement about how regularly these types of incidents happen. Second, EPA's risk assessments and registration decisions are based on the premise that the WPS protections effectively prevent people (workers and bystanders) from being sprayed directly (Ref. 13). In other words, incidents where workers or bystanders are sprayed directly result in people being exposed to pesticides in a way that is not considered in EPA's risk assessments or registration decisions. These types of incidents are misuse violations but they continue to occur, as described in the following sections. Therefore, there is a need to supplement the existing WPS protections to reduce exposures to workers and other persons from being directly sprayed with pesticides.

EPA agrees with the farm bureau commenter that there are many factors that can cause exposure to drift and there is no one solution that can prevent all drift incidents. It will take a

comprehensive approach, including additional regulatory requirements, education, outreach, and some common-sense voluntary measures to further reduce the number of people who are directly exposed to pesticide spray/applications. The additional regulatory requirements include revised requirements for entry restrictions during pesticide applications and for handlers to suspend applications in certain circumstances. Common-sense voluntary measures include improving communications about when a pesticide application will take place by a grower talking to his/her neighbors to let them know when pesticides are being applied so the neighbors can keep workers and others away from the boundary of adjacent establishments during that time, and by participating in voluntary communication programs such as Spray Safe (http://www.spraysafe.org/) and Drift Watch (https://driftwatch.org/).

In response to the comments that EPA should require agricultural establishments to inform their neighbors about pesticide applications, EPA notes that it did not propose such a requirement. Because of the potentially far-reaching impact a broad notification requirement could have on all agricultural establishments that apply pesticides, EPA believes that such a change would warrant public notice and comment before being added to the WPS, and therefore has not included it in the final rule. EPA intends to include notice to neighbors among information about good management practices during outreach for implementation of the final rule.

It is also worth noting that EPA is working to assess and mitigate any product-specific risks from exposure to pesticides from drift and from volatilization within the registration review process. Also, EPA has proposed changes to the pesticide applicator certification regulations to include more training and a requirement for applicators using certain higher risk application methods, such as aerial application and fumigation, to obtain a specialized certification. (80 FR 51355, August 24, 2015) This should improve the competency of applicators and decrease the incidents caused by applicator carelessness. EPA agrees that rigorous enforcement of existing and new WPS provisions and label requirements are necessary and has committed to a robust outreach, communication and training effort to communicate the new rule requirements to state, tribal and regional staff as well as the affected WPS stakeholders and will work closely with our state and tribal partners to enforce the WPS in the future. In 2014, EPA launched its voluntary drift reduction technology program (http://www2.epa.gov/reducing-pesticide-drift), which is intended to encourage the development and use of validated low drift technologies.

EPA has not reviewed the 76 drift cases from California that were mentioned by several commenters in detail. However, it is possible that at least some of them would be prevented by the final rule requirement for the handler to suspend application because that requirement extends beyond the boundaries of the establishment, as explained in Unit VII.C.

B. Entry Restrictions to Protect Workers and Other Persons During Application

1. Current rule and proposal. The existing WPS establishes entry-restricted areas adjacent to treated areas that apply during pesticide application for nurseries and greenhouses only. The existing rule requires that the agricultural employer must not allow or direct any person, other than an appropriately trained and equipped handler, to enter or remain in the entry-restricted area during a pesticide application in a nursery or greenhouse. The size of the entry-restricted area depends on the type of product applied and the application method. The entry restrictions for greenhouses also include ventilation requirements. The existing entry restriction requirement applies only within the boundaries of the agricultural establishment. The existing provisions at 40 CFR 170.110 regarding entering entry-restricted areas during application are different than the existing provisions at 40 CFR 170.112 regarding entry into treated areas after the application of a pesticide and before the REI specified on the pesticide labeling has expired.

EPA proposed to establish entry-restricted areas during pesticide applications on farms and in forests, while slightly modifying the requirement for entry-restricted areas for nurseries and greenhouses. EPA proposed two types of entry restrictions: One for enclosed space production, which would apply to greenhouses and other types of indoor production operations (e.g., mushroom houses, hoop houses, polyhouses), and one for outdoor production, which would apply to farms, forests and nurseries. In addition, EPA proposed to define the entry-restricted area as the area from which workers or other persons must be excluded <u>during and after</u> the pesticide application.

2. Final rule. In regard to enclosed space production (e.g., greenhouses, mushroom houses, hoop houses), EPA has finalized the requirements for entry restrictions during pesticide applications with several minor changes. For the most part, the final rule incorporates the existing entry restriction and ventilation requirements for greenhouses as the requirements for enclosed space production. The final rule deletes the term "entry-restricted area" and adjusts the descriptions of the application types to be consistent with the changes to the description of application exclusion zones for outdoor production. In addition, EPA changed the definition of "enclosed space production" to clarify that it applies only to areas with non-porous covering, so structures with a covering made of fencing or fabric to provide shade on plants (no walls) such as shade houses, are not considered enclosed spaces under the final rule. See the discussion of definitions in Unit XVIII.C. of this document for more information about the changes to this definition.

In regard to outdoor production (e.g., farms, forests, nurseries, shade houses), the final rule differs substantially from EPA's proposed requirements. The final rule makes the following changes from the proposal:

- Replacing the phrase "entry-restricted area" with "application exclusion zone" to make it more distinct from the requirements regarding REIs. The final regulatory text for this requirement is available at 40 CFR 170.405(a).
- Revising the corresponding definition to clarify that the application exclusion zone exists only during (not after) a pesticide application. The final regulatory text for this definition is available at 40 CFR 170.305.
- Revising the corresponding definition and regulatory description of an application exclusion zone so it is a specified distance from the application equipment rather than from the edge of the treated area, and clarifying that the application exclusion zone moves with the application equipment. The final regulatory text for this requirement is available at 40 CFR 170.405(a)(1).
- Revising some of the application methods in the description of the application exclusion zone to reflect current application methods and to differentiate the distances based on the spray droplet size rather than pressure. The final regulatory text for this requirement is available at 40 CFR 170.405(a)(1).
- Adding a provision to the regulatory text to clarify that any labeling restrictions supersede the requirements of the WPS, including those related to application exclusion zones. This was discussed in the preamble of the proposed rule (Ref. 2 at 15490) but was inadvertently left out of the proposed regulatory text. The final regulatory text for this requirement is available at 40 CFR 170.303(c) and 170.317(a).
 - 3. Comments and responses.

<u>Comments – supporting the proposal or more stringent measures.</u> Many commenters, including farmworkers, farmworker advocacy organizations, public health organizations, state pesticide regulatory agencies and a university, generally supported the proposed requirement for entry-restricted areas. The commenters stated that the proposed change should provide modest improvements in protecting workers from pesticide drift during application if there is enough training and education of applicators.

One farmworker advocacy organization described an incident where workers were in a field topping tobacco at the same time a plant growth regulator with a 24-hour REI was being applied to the adjacent row. The workers were close enough to have to move out of the path of the tractor. However, because the treated area was defined to be only the rows being treated, this was permissible under the existing WPS. Many commenters provided other examples of incidents where workers were unintentionally exposed directly to the pesticide spray. A few farmworker advocacy organizations commented that many workers say that they have felt the spray of pesticides from fields close to where they work. A farmworker advocacy organization commented that in 2012, about 20% of farmworkers surveyed by the organization in New Mexico reported that pesticides were applied to the fields at the same time that they were working. Another farmworker advocacy organization stated that about half of the child tobacco workers interviewed by the organization in 2013 reported that they saw tractors spraying pesticides in the fields in or adjacent to the ones where they were working.

Many commenters, including farmworker advocacy organizations, public health organizations, state departments of health and universities argued that EPA should revise the approach for entry restrictions to protect workers on neighboring property and to increase the length of the entry-restricted area. The recommended distances ranged from 60 to 200 feet for ground application and 300 feet to a mile or more for aerial application. Many of these commenters also stated that EPA should protect workers the day after the application, claiming that pesticide would be volatilizing off the field. EPA addressed similar suggestions in its response to "Pesticides in the Air – Kids at Risk: Petition to Protect Children from Pesticide Drift (2009)" by describing EPA's current methodologies for assessing the risks to bystanders from exposure to pesticides from drift and from volatilization and how EPA will address risks of concern via the registration review process (Ref. 13).

Comments – opposing the proposal. Many states and their organizations, grower organizations, farm bureaus, applicators and their organizations, agricultural producer organizations, pesticide manufacturer organizations, and the SBA Office of Advocacy opposed the proposed requirement to apply the entry-restricted areas to farms and forests. Most of these commenters argued that the approach is too complicated because it establishes another area to be controlled that varies by application type, may include persons other than those employed by the agricultural establishment and may be different than label restrictions. Some states and their organizations commented that the requirement to keep individuals out of varying widths of areas surrounding treated areas would be difficult for an agricultural employer to implement and even more difficult for a state to enforce. Several state agencies and a farm bureau commented that the tables describing the entry-restricted area are too complex to communicate and implement. Another state agency opposed the term "entry-restricted area" because it is not clear and recommended calling it exactly what it is, a restricted area. A state pesticide regulatory agency in the Midwest commented that they have not documented an incident of worker exposure from drift and suggested that the incident data from California should not be the basis of a national requirement.

Most of these commenters asserted that the proposed requirement to apply entry-restricted areas to farms and forests would present some logistical issues that could effectively shut down parts of the establishment. For example, many ground and aerial pesticide applications occur along rural roads or near access points to the agricultural establishment. These roads and access points would be within the proposed entry-restricted areas. On larger fields, pesticide applications could take several hours to complete. Commenters claimed that prohibiting workers from using these roads or gaining access to buildings on agricultural establishments such as farms or nurseries for long periods of time would be impractical, could cause the establishment to shut down during applications and could have an adverse

economic impact. Many commenters, including state pesticide regulatory agencies and their organizations and grower organizations, opposed the proposal stating that work in nearby fields or forest blocks would be impossible during pesticide applications. Many of the commenters stated that EPA did not account for the cost of stopping business during some pesticide applications. Several commenters, including state pesticide regulatory agencies, grower organizations, applicators and their organizations, and a pesticide manufacturer organization, commented that the entry-restricted area should account for the wind direction because any exposure would only occur downwind.

A farm bureau commented that a buffer seems reasonable if workers are near a sprayer making an application and suggested that the buffer should be from the sprayer, not the edge of the field. A grower organization argued that the proposed entry-restricted area requirement is not necessary because they already move workers away from areas being sprayed to avoid contact from overspray and fumes. Several applicator organizations commented that aerial applicators often apply pesticides to large farms and forests where workers are seldom present.

Some of the comments appear to reflect a misunderstanding of the proposal, i.e., that the entry-restricted areas would be "buffer zones" that would remain in effect after the application was complete. As an example, one grower organization opposed the "worker buffers" because they could take a lot of area out of cultivation on smaller farms, farms with widely varied crop maturities and farms that are not laid out in large blocks that could not space crops to accommodate this restriction. Instead of arbitrary buffers, this commenter argued to keep the standard as it is - do not apply where workers are present and do not allow spray (or drift) to contact workers. Another commenter asked EPA to revise the entry-restricted area to require workers to not be present when the application is occurring. A farm bureau commented that there is little reason for the expanded entry-restricted areas to exist once the pesticide has been applied. A state regulatory agency claimed that the proposed entry-restricted area would significantly impact agricultural practices and increase pest pressure due to untreated areas. A grower organization and a farm bureau commented that the proposed entry-restricted area could cause concerns among neighbors of farms by encouraging the impression that similar "buffer zones" are necessary between areas receiving pesticide applications and adjacent public areas.

The SBA Office of Advocacy recommended that EPA remove the proposed entry-restricted areas for farms for many of the reasons cited in this and the previous section: current regulations already provide protections, EPA's risk assessments include protections on the label, the requirement could be confusing, and the proposed requirement could block roads which would disrupt operations on the agricultural establishment.

Comments on application types and distances. Some commenters addressed the specific application methods and the distances of 100 feet and 25 feet in the proposed entry-restricted areas. Some commenters, including states and their organizations, grower organizations, agricultural organizations and pesticide manufacturer organizations commented that the distances of 25 to 100 feet are not supported by drift reduction technologies, applicator standard operating procedures or incident data. A pesticide manufacturer organization commented that fumigants should be excluded from the entry-restriction area requirements because they are addressed individually with more detailed restrictions. A state regulatory agency commented that the label should take precedence if it has buffers for human exposure. A state commented that the table of application methods and distances is flawed because it does not account for all application scenarios and does not logically apply distances. For example, tower-type sprayers are generally at the height of the tree canopy and spray horizontally into trees at a pressure under 150 psi. The proposed entry-restricted area for these would be 0 feet,

although the state commented that there should be a buffer because of the height of the application. The state also pointed out that some chemigation systems may require a 100-foot entry-restricted area. This state and a grower organization pointed out that the distances do not account for canopy cover, which can affect how far a spray droplet travels.

EPA Response. Based on the comments, EPA has made some changes in the final rule from the proposed requirement to extend entry-restricted areas to farms and forests. However, experiences such as those of workers having to move to get out of the way of the tractor that was applying pesticide (described previously) and workers being directly sprayed confirm EPA's position that additional protections are necessary during pesticide applications on farms and in forests. The existing WPS prohibits a farm or forest agricultural employer from allowing or directing any worker to enter or remain in a treated area, which is defined to include areas being treated. The existing regulations require oral notifications before pesticide applications to include the location and description of the treated area, the time during which entry is restricted and instructions not to enter the treated area until the REI has expired. The existing regulations require handler employers to ensure that pesticides are applied in a manner that will not contact a worker either directly or through drift. Inasmuch as these requirements – clearly intended to prevent direct exposure of workers during pesticide applications – have proven insufficient for that purpose, additional measures are needed.

EPA has changed the final rule in several ways to address some of the concerns expressed in the comments about the logistical problems with the proposal. First, in the final rule EPA replaced the term "entry-restricted area" with "application exclusion zone," which more clearly associates this restriction with the period during the pesticide application. This new term is also less likely to be confused with the term "restricted-entry interval." Second, EPA revised the requirements for the application exclusion zone so that it is not based on the "treated area," but instead a specified distance from the application equipment as suggested by one of the farm bureau commenters. The application exclusion zone is essentially a horizontal circle surrounding the application equipment that moves with the application equipment. For example, if a pesticide is applied aerially, the border of the application exclusion zone is a horizontal circle that extends 100 feet from the place on the ground directly below the aircraft, and moves with the aircraft as the application proceeds. Third, EPA simplified the requirement for application exclusion zones for outdoor production by deleting the table and simplifying the description of the application exclusion zone.

Because the application exclusion zone is based on the location of the application equipment, rather than the location of the treated area, the application exclusion zone could extend beyond the boundary of the agricultural establishment. However, in 40 CFR 170.405(a)(2), the final rule limits the requirement for the agricultural employer to keep workers and other persons out of the treated area or the application exclusion zone during application to areas that are within the boundaries of the agricultural establishment, as proposed. The existing entry-restricted area requirement for nurseries is also limited to areas that are within the boundaries of the agricultural establishment. EPA retained the existing and proposed limitation because this requirement applies to the agricultural employer. The agricultural employer can control what happens on the agricultural establishment but could have difficulty limiting access to roads or fields that are beyond his property.

Limiting the application zone to the area closest to the application equipment eliminates the concerns expressed by many commenters, including the SBA Office of Advocacy, about shutting down roads or closing off buildings for the entire time the field or other area is being treated or preventing work in nearby fields. The approach in the final rule does not account for wind direction, although the final rule specifies a much smaller area that agricultural employers must keep workers and other people

from than the existing WPS and the proposed approach. The approach in the final rule will be easy to comply with for growers that already move workers away from areas to be sprayed to avoid contact. Unfortunately, not all growers do this as shown by the example of the workers in the tobacco field who had to move out of the way of the sprayer. Similarly, if workers are not present, it will be easy for agricultural employers to keep them out of the application exclusion zone during the application.

The comments reflected a general lack of understanding that the proposed entry-restricted areas would exist only during application, and many comments anticipated conflicts between no-spray buffers on some pesticide labels and the proposed entry-restricted area and expressed concern about areas needing to be taken out of production to stay 25 feet or 100 feet away from the adjacent field. However, these are two different types of requirements. If a label specifies a "no-spray" buffer, pesticide cannot be applied in that area at any time. Under the final rule, a pesticide can be applied in an application exclusion zone, and the requirement for agricultural employers is to keep workers and other people out of this zone during the pesticide application. These two types of requirements are distinct, and as a result should not be problematic to implement. Further, the application exclusion zone only applies (and the proposed entry-restricted area would have applied) only during the pesticide application and does not exist once the application is over.

EPA reassessed the application methods and distances in the proposed requirements for entry-restricted areas for outdoor production and made some changes in the description of application exclusion zones in the final rule in § 170.405(a)(1). The final rule maintains the proposed distances of 100 feet and 25 feet but revises the application methods associated with each distance.

The application methods that have an application exclusion zone of 100 feet are the ones where pesticide is expected to move a longer distance from where they are applied. The changes include:

- Adding air blast applications, to more accurately and more broadly describe current application methods.
 - Deleting pesticides applied as an aerosol because it is unnecessary.
- Including pesticides applied as a spray using a spray quality (droplet spectrum) of smaller than medium (volume median diameter less than 294 microns). The volume median diameter refers to the midpoint droplet size or mean, where half of the volume of spray is in droplets smaller, and half of the volume is in droplets larger than the mean. EPA chose to establish this criteria based on the spray quality rather than just the pressure because the drop size depends on a number of variables, including the pressure, the nozzle type, liquid properties, and the spray angle. Focusing on the spray quality, rather than pressure, is also consistent with EPA's voluntary Drift Reduction Technology program and current models of drift used in EPA's risk assessments.

The application methods that have an application exclusion zone of 25 feet are the ones where pesticide is expected to move a shorter distance from where they are applied. The changes include:

- Replacing several of the proposed criteria with pesticides applied as a spray using a spray quality (droplet spectrum) of medium or larger (volume median diameter of 294 microns or larger).
- Eliminating the criterion based on the product label requiring a respirator because it is intended to apply to enclosed spaces like greenhouses and was accidentally included in the proposed criteria for outdoor production.
- Eliminating the proposed requirement for the spray to be applied downward, so tower-type sprayers would be subject to an application exclusion zone of 25 feet or 100 feet, depending on the spray droplet spectrum.

The corresponding changes to application methods were made to the Table – Entry Restrictions During Enclosed Space Production Pesticide Applications at 40 CFR 170.405(b)(4) for consistency.

EPA acknowledges that some pesticide labels will have restrictions that apply during applications that are different than the application exclusion zones. For example, the restrictions on soil fumigant labels are more restrictive than the application exclusion zone of 100 feet specified in § 170.405(a)(1)(i)(D). In situations like this, pesticide users must follow the product-specific instructions on the labeling. As stated in §§ 170.303(c) and 170.317(a), when 40 CFR Part 170 is referenced on a pesticide label, pesticide users must comply with all of the requirements in 40 CFR Part 170, except those that are inconsistent with product-specific instructions on the pesticide product labeling.

Although the size of the application exclusion zone does not vary based on the amount or type of canopy cover, EPA believes that the changes from the proposed rule will provide appropriate application exclusion zones in almost all use situations. While additional refinements to account for canopy cover might offer some advantages, those advantages would be offset by the additional complexity they would add to the rule.

C. Suspend Application

- 1. Current rule and proposal. As discussed in Unit IX.A., the existing WPS requires handler employers and handlers to assure that no pesticide is applied so as to contact, either directly or through drift, any worker or other person, other than an appropriately trained and equipped handler. However, the existing WPS does not include an explicit requirement for handlers to stop or suspend application. EPA proposed to add a provision to require a handler performing a pesticide application to immediately stop or suspend the pesticide application if any worker or other person, other than an appropriately trained and equipped handler, is in the treated area or the entry-restricted area. Based on the description of entry-restricted areas in the proposed rule, the requirement for handlers to stop or suspend application in certain circumstances would apply only within the boundaries of the agricultural establishment.
- 2. Final rule. In the final rule, EPA has made several changes to the proposed requirement to suspend applications. First, EPA revised the language to require a handler to "immediately suspend a pesticide application" rather than to "immediately stop or suspend a pesticide application" to clarify that the application must be suspended but can be restarted once workers or other persons are out of the zone. Second, EPA changed the area that is covered by the requirement to suspend application in two ways. EPA replaced "entry-restricted area" with "application exclusion zone," decreasing the size of the area that is covered by the requirement. See Unit IX.B. Also, EPA removed the treated area from the requirement. For outdoor production, the area covered by the requirement is much smaller than the area that would have been covered by the proposed rule, which would have been the treated area plus up to 100 feet beyond the edge of the treated area. Third, the application exclusion zone can extend beyond the boundaries of the agricultural establishment for the purposes of this requirement, i.e., the handler must suspend application if any person other than another handler involved in the application is in the application exclusion zone, regardless of whether the application exclusion zone extends off of the employer's property.

The final rule requires the handler performing the application to suspend application if people who should not be present are in the application exclusion zone (which ranges up to 100 feet from the application equipment for outdoor production) or in the area identified for exclusion for enclosed space production (which ranges from 25 feet to the entire enclosed space plus any adjacent structure that cannot be sealed off). The final regulatory text for this requirement is available at 40 CFR 170.505(b).

3. Comments and responses.

<u>Comments</u>. Many commenters, including farmworkers, farmworker advocacy organizations, public health organizations, academics, a public health agency and state pesticide regulatory agencies

generally supported the proposed requirement for applicators to stop or suspend pesticide applications under certain conditions. A farmworker advocacy organization supported the proposed requirement, stating that current rules do not provide meaningful guidance on how applicators can prevent human exposure during applications. Many commenters from farmworker advocacy organizations, public health organizations, public health agencies and universities supported the proposed requirement but urged EPA to extend the protections to workers at neighboring establishments. Many of these commenters provided information suggesting that workers may be more likely to be affected by drift from a different establishment. For example, commenters cited a Washington Department of Health report that documented 43 workers in Washington being affected by drift from another farm while only 13 workers reported being affected by drift from the farm where they were working in 2010-2011. In comments arguing against the need for entry-restricted areas, several applicator organizations provided examples supporting the requirement to suspend applications, stating that it is standard operating procedure for aerial applicators to temporarily avoid making passes adjacent to roads or other areas if workers happen to be passing by in vehicles or on foot.

Three comments from Washington – the state pesticide regulatory agency, the state farm bureau and a grower organization – pointed out that the Washington drift incident cited in the preamble of the proposed rule would not have been prevented by the proposed requirement for applicators to cease or suspend pesticide application if workers or other people were in the entry-restricted area. This is because the workers were on a neighboring farm and under the proposal, the entry-restricted area would stop at the border of the establishment where the pesticide is being applied.

Many states and their organizations, grower organizations, farm bureaus, applicator organizations, agricultural producer organizations and pesticide manufacturer organizations opposed the proposed requirement for handlers to stop or suspend pesticide applications in certain circumstances. Most of these commenters argued that the provision is unnecessary because it would not offer any protections or prevent contact from pesticide applications beyond the existing "do not contact" requirement. Some commenters raised logistical concerns: Applicators may not be aware that a person has entered a treated area or entry-restricted area in many situations, such as in a forest or an orchard in full leaf, in a very large field, or if there are restricted sight lines or rolling hills; the proposed requirement would impose unwarranted expectations for pilots, who would have to be fully aware of boundaries 100 feet on all sides of the target area while traveling at 150 mph; as proposed, an applicator would have to stop if a person is in an entry-restricted area even if it is not possible for that person to encounter pesticides because of wind conditions. Many commenters, including state pesticide regulatory agencies and their organizations, a grower organization, a farm bureau, a pesticide manufacturer organization and applicator organizations, asked how an applicator would know if a person in the entry-restricted area is an appropriately trained and equipped handler, who could legally be in the entry-restricted area during application.

A few grower organizations and farm bureaus commented that there is a difference between stopping and suspending an application and asked whether this would require applicators to cease application altogether or suspend the application until a person is no longer in the area.

<u>EPA Response</u>. As stated in the proposal, EPA has identified a need to supplement the "do not contact" performance standard because exposure to drift or direct spray events still happen despite the "do not contact" requirement, and EPA's risk assessments and registration decisions presume that no workers or other persons are being sprayed directly. Therefore, the final rule includes an explicit requirement for handlers to suspend pesticide applications under certain conditions, which mandates applicators to take specified actions to prevent exposing people to pesticide during applications.

However, EPA revised the final rule in response to several points made by commenters. First, the final rule requires a handler to "immediately suspend a pesticide application" rather than to "immediately <u>stop or</u> suspend a pesticide application." This change was made to clarify that the application must be suspended immediately if workers or persons other than handlers are in the specified areas but can be restarted once workers or other persons are out of the specified area.

EPA was persuaded by the commenters who raised logistical concerns about the proposed requirement, which were related to the handler not being able to see the person or a person entering an edge of a large area that is not near the application equipment. EPA revised the requirement in the final rule to decrease the size of the area that the handler must monitor for workers or persons other than handlers by removing the treated area from the area covered by this requirement and by changing the "application exclusion zone" so it is measured from the application equipment rather than from the edge of the treated area. In the final rule, the handler performing the application must suspend application if any of the identified people are in the application exclusion zone (which ranges up to 100 feet from the application equipment) rather than if any of the people are in the entire treated area plus that distance (up to 100 feet) from the edge of the treated area. EPA acknowledges that there will be situations where the handler (applicator) legitimately cannot see a person 100 feet away, such as in a dense orchard or a forest. During the review of incident cases for the benefit analysis, there were several cases where a person in an orchard was exposed to pesticides applied aerially. EPA assessed those cases as not preventable by WPS because this requirement would not change the fact that the applicator could not see the person in the orchard. When EPA updates the WPS Inspector Guidance, we will discuss mitigating circumstances such as the inability of an applicator to see the worker or person in the application exclusion zone, as well as information about how this requirement can be enforced.

In response to the questions regarding how an applicator would know if a person in the entry-restricted area is an appropriately trained and equipped handler who could legally be in the entry-restricted area during application, the answer is that if the applicator is not certain, he or she must suspend application. EPA presumes that the only trained handlers present in or around the treated area and wearing the PPE appropriate for the pesticide being applied would be handlers who are participating in the application, and further presumes that each handler should be aware of all other appropriately trained and equipped handlers participating in that same application. EPA notes the idea that an appropriately trained and equipped handler is in the existing WPS at §170.110(a) and §170.210(a) so agricultural employers, handler employers and handlers should know how to identify an appropriately trained and equipped handler after 20 years of experience with the WPS.

EPA was also persuaded by the comments and incident information about workers at neighboring establishments being directly contacted by drift and acknowledges that the Washington State drift incident cited in the preamble of the proposed rule would not have been prevented by the proposed entry-restricted area, which would have been limited by the boundaries of the agricultural establishment. The incidents cited by commenters show that workers are directly exposed to pesticide applications from neighboring establishments as well as from the establishment where they are working. To reduce the number of incidents where workers are exposed to drift from neighboring establishments, the final rule extends the application exclusion zone beyond the boundaries of the agricultural establishment for this requirement, thus requiring applicators to immediately suspend applications if people other than a properly trained and equipped handler are in the application exclusion zone.

EPA has decided to extend the application exclusion zone beyond the boundaries of the agricultural establishment for the requirement to suspend applications for several reasons. First, this

addresses more of the worker drift cases, where workers are within 100 feet of the agricultural establishment to protect more workers. Out of 17 incidents identified in the comments, only one would have been prevented if the application exclusion zone was limited to the boundaries of the agricultural establishment as provided in the proposed rule. The requirement in the final rule would have prevented at least four of the incidents reported in the comments, and possibly as many as 12, depending on the actual distances between the workers and application equipment, which were not specified in the comments. Second, the existing requirement that the handler must assure the pesticide is applied in a way that does not contact workers or other persons already extends beyond the boundary of the agricultural establishment. The new, explicit requirement to suspend application if people other than handlers are in the application exclusion zone is intended to supplement the existing "do not contact" requirement by giving the applicator specific criteria for suspending application. These specific criteria should be equally useful to applicators attempting to comply with the existing "do not contact" requirement beyond the boundaries of the agricultural establishment. Third, the application exclusion zone would extend a maximum of 100 feet beyond the boundary of an agricultural establishment only for the length of time it takes for the equipment applying the pesticide to pass by, so this should not shut down roads or access points to the establishment for long periods of time. To reiterate a point made in Unit IX.B., the final rule does not hold agricultural employers responsible for keeping workers and other persons out of portions of the application exclusion zone that extend beyond the boundaries of the agricultural establishment. On the other hand, this provision in § 170.505(b) of the final rule imposes a requirement on the handler applying the pesticide to immediately suspend the application if workers or persons other than handlers involved in the application are in the application exclusion zone, whether on the establishment or beyond the boundaries of the establishment.

X. Establish Minimum Age for Handling Pesticides and Working in a Treated Area while an REI is in Effect

A. Current Rule and Proposal.

The existing regulation does not establish any age restriction for handlers or early-entry work. EPA proposed to prohibit persons younger than 16 years of age from handling pesticides, with an exception for handlers working on an establishment owned by an immediate family member. EPA requested comment on an alternative option of prohibiting any person under 18 years old from handling pesticides.

The existing WPS establishes conditions for when a worker may enter into a treated area under an REI. The conditions are related to the type of work performed (often referred to as "early-entry" tasks) and the length of time the worker may be in the treated area. However, the existing WPS establishes no minimum age for workers entering a treated area under an REI to perform early-entry tasks. EPA proposed to prohibit any worker under 16 years old from entering a treated area under an REI to perform early entry tasks, with an exemption from this prohibition for persons covered by the immediate family exemption. EPA requested comment on an alternative option of prohibiting any person under 18 years old from entering treated areas during the REI to perform early entry tasks. *B. Final Rule*.

The final rule prohibits persons younger than 18 years old from handling pesticides. EPA has retained the proposed exemption for handlers working on an establishment owned by an immediate family member. The final regulatory text for the prohibition is available at 40 CFR 170.309(c) and 170.313(c). The final regulatory text for the exemption is available at 40 CFR 170.601(a)(1)(i).

The final rule prohibits persons younger than 18 years old from entering treated areas during the REI to perform early entry tasks, and retains the proposed exemption for persons working on an establishment owned by an immediate family member. The final regulatory text for this prohibition is available at 40 CFR 170.309(c) and 170.605(a). The final regulatory text for the exemption is available at 40 CFR 170.601(a)(1)(xii).

C. Comments and Responses.

Comments. Many commenters requested that EPA establish a minimum age of 18 for handlers and early-entry workers. Commenters cited several reasons for their request. First, many commenters noted that adolescents' bodies are still developing and they may be more susceptible to the effects of pesticide exposure. Second, commenters noted that adolescents are less mature and their judgment is not as well developed as that of adults. This immaturity may mean that adolescents may be less consistently aware of risks associated with handling pesticides or entering a treated area while an REI is in effect, that they may not adequately protect themselves or other workers from known risks, and that spills, splashes, and improper handling practices may be more likely. In addition, some of these commenters noted that adolescents may lack the judgment or confidence to refuse to perform a task that places them at risk if asked by an adult in authority. A few commenters submitted studies related to development of maturity and decision-making skills in adolescents in support of this assertion. Third, commenters asserted that restricting handling activities to persons at least 18 years old could result in higher potential economic benefit from avoiding exposure and any potentially related chronic effects to children, because they have a longer potential life span. Fourth, because information on the potential chronic effects of pesticide exposure on developing systems is not known, commenters recommended that EPA prohibit adolescents from handling pesticides and entering treated areas while an REI is in effect as a precaution until it can be shown that they would not suffer adverse chronic effects from potential exposure. Finally, a few commenters noted that persons under 18 years old are protected in other industries by OSHA and should receive similar protections under the WPS, and that some states have already prohibited handling of pesticides in agriculture by anyone under 18 years old.

Some commenters expressed support for a minimum age of 16. States primarily supported EPA's proposal to establish a minimum age of 16, noting that establishing a minimum age of 18 would require them to change their state laws. Other commenters supporting the proposed minimum age of 16 noted that this requirement would align with DOL's restriction on handling pesticides in toxicity categories I and II in agriculture.

A few commenters supporting establishing a minimum age of either 16 or 18 noted that a specific minimum age requirement would be easy to remember and enforce.

A few commenters suggested establishing a higher minimum age (either 20 or 21) for handlers and early entry workers, or only for people using RUPs.

A few commenters opposed establishing any minimum age. These commenters asserted that EPA should not take any action because the DOL's hazardous occupations orders under the Fair Labor Standards Act (FLSA) already prohibit adolescents under 16 years old from handling pesticides in toxicity categories I and II in agriculture with limited exceptions. Some commenters also asserted that establishing any minimum age for pesticide handlers is a matter that should be handled by the states, not EPA. A few commenters suggested that rather than EPA setting a minimum age, the WPS requirements should be aligned with each state's laws and regulations related to minimum age.

Some commenters requested that EPA eliminate the exception from any minimum age requirement for members of the owner's immediate family. Commenters assert that adolescents' developmental status does not differ if they are an employee on a farm owned by an immediate family

member or by someone unrelated to them. Other commenters supported EPA's proposal or requested that EPA establish a higher minimum age only if EPA also retains the exception for members of the owner's immediate family.

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EPA Response. Based on the comments received and an evaluation of existing literature related to adolescents' development of maturity and judgment, EPA has decided that the benefits of further reductions in adolescent pesticide exposures justify their cost; the final rule generally prohibits persons under 18 years old from handling pesticides or entering a treated area while an REI is in effect. EPA recognizes that adolescents' bodies and judgment are still developing. While studies have not demonstrated a clear cut off point at which adolescents are fully developed, literature indicates that their development may continue until they reach their early to mid-20s. EPA also agrees that research has shown that adolescents may take more risks, be less aware of the potential consequences of their actions on themselves and others, and be less likely to protect themselves from known risks. In addition, EPA recognizes that adolescents may not feel empowered to question or refuse tasks assigned to them that would put them at risk. All of this information supports establishing a higher minimum age than proposed in order to allow those handling pesticides to develop more fully before putting themselves, others, and the environment at risk, and to allow those performing early-entry activities to develop more fully in order to adequately protect themselves from the risks of entering a treated area while an REI is in effect. EPA agrees that establishing a consistent minimum age for handlers and early-entry workers would be easy to remember and enforce. The final rule will reduce the potential for misuse by adolescent handlers who may less consistently exercise good judgment when handling agricultural pesticides.

EPA notes commenters' assertions that avoiding pesticide exposure in adolescents could result in higher potential economic benefit because of adolescents' longer potential lifespans. EPA agrees that it is appropriate to take reasonable precautions to protect adolescents from pesticide exposures, both because of the potential impact of pesticides on further development and because adolescents may not properly appreciate (and take appropriate steps to avoid) the risks of potential pesticide exposure. While statistical associations have been observed in studies that estimate the relation between pesticide exposure and chronic health outcomes such as cancer, the causal nature of these associations has not yet been determined; thus quantifying the magnitude of the chronic health risk reduction expected as a result of pesticide exposure reduction is not possible. However, based on what is known about the potential for biologically active chemicals generally to disrupt developmental processes, it is reasonable to have heightened concern for adolescents under the age of 18 in situations where they face particularly high pesticide exposures. Prohibiting adolescents under the age of 18 from handling agricultural pesticides will protect them from any potential risks of pesticide use through handling activities, ensuring that adolescents do not suffer unreasonable adverse effects from handling agricultural pesticides. Prohibiting adolescents under 18 years old from entering a treated area while an REI is in effect will protect them by delaying their entry into treated areas until residues are at a level that should not cause unreasonable adverse effects.

EPA recognizes that DOL prohibits persons under 18 years old from engaging in hazardous tasks in other industries, and that some states have taken action to prohibit certain adolescents from handling pesticides in agriculture (state minimum ages for pesticide handlers, where established, range from 16 years old to 18 years old). These examples of protections for adolescents in other industries or by states indicate a recognition that different standards for certain adolescents and adults are appropriate.

EPA disagrees with commenters' request to establish a minimum age higher than 18. While research shows that brains continue to develop until people are in their early to mid-20s, the minimum

age to engage in many hazardous activities has been established as 18 years old. For the reasons outlined above, in addition to the lack of recognition in other industries that people must be at least 20 or 21 to conduct certain risky occupational tasks, EPA disagrees with commenters' requests to establish a minimum age higher than 18 years old. In addition, EPA notes that limitations on the use of RUPs falls under a different regulation, the Certification of Pesticide Applicators rule. Persons using restricted use pesticides in agriculture could be covered by both the WPS and the Certification of Pesticide Applicators rule. EPA has proposed establishing a minimum age for all users of RUPs under that rule (80 FR 51355, August 24, 2015).

EPA also disagrees with commenters' assertions that EPA should defer to the states or the FLSA and not establish any age-related restrictions on pesticide handling or early-entry activities. EPA has the responsibility under FIFRA to regulate the use of pesticides to avoid unreasonable adverse effects, apart from any requirements established by other federal or state laws. The DOL's actions under the FLSA limiting the use of certain pesticides to persons at least 16 years old do not preclude EPA from taking actions to ensure that human health and the environment are protected from unreasonable adverse effects. While DOL's hazardous occupations order prohibiting those under 16 years old from handling certain pesticides satisfies the purposes of the FLSA, those purposes are distinct from those of FIFRA. EPA has concluded that because, as discussed previously, adolescents' bodies, maturity, and judgment are still developing, the handling of agricultural pesticides and entry into a treated area while an REI is in effect by persons under 18 years old presents an unreasonable likelihood of adverse effects. Therefore, the final rule generally limits pesticide handling and early-entry activities to persons who are at least 18 years old.

EPA agrees that adolescents' developmental status does not differ if they are employees on a farm owned by an immediate family or by someone unrelated to them. However, EPA recognizes that imposing a minimum age for handling agricultural pesticides or performing early-entry tasks on owners or members of their immediate families could significantly disrupt some immediate family-owned farms. Given the high social cost of imposing a minimum age requirement on farms owned by members of the same immediate family, EPA has finalized the proposed exemption to this requirement. See Unit XVII.A.

XI. Restrictions on Worker Entry into Treated Areas

A. Requirements for Entry During an REI

1. Current rule and proposal. The existing WPS establishes specific exceptions to the general prohibition against sending workers into a treated area while an REI is in effect. Workers who enter pesticide-treated areas during an REI (known as "early-entry workers") without adequate protection may face an elevated risk from pesticide exposure. Under the existing rule, the employer must: Ensure that the worker has read or been informed of the human health hazards on the product labeling; provide instruction on how to put on, use, and remove PPE; stress the importance of washing after removing the PPE; and instruct the worker on how to prevent, recognize, and treat heat-related illness. The employer must also implement measures to prevent heat related illness when workers must wear PPE.

In addition to these existing requirements, EPA proposed to require employers to inform workers sent into a treated area while the REI is in effect of the specific exception under which they would enter, to describe the tasks permitted and any limitations required under that exception, and to identify the PPE required by the labeling. EPA also proposed to require the employer to create a record of the oral notification provided to early-entry workers, to obtain the signature of each early-entry worker acknowledging the oral notification prior to the early entry, and to maintain the record for 2

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2. Final Rule. EPA has finalized the proposed requirements for the employer to inform the worker of the type of exception which permits the entry into the area under an REI, to describe the tasks that the worker may perform and other limitations under the exception, and to identify the PPE that must be worn. However, EPA has decided not to require employers to create or maintain records of the oral notification. The final regulatory text for this requirement is available at 40 CFR 170.605.

3. Comments and responses.

Comments on oral notification. Comments on the proposal to inform workers of the early-entry exception and to explain the PPE were largely supportive, recognizing the reasonable nature of the proposed information. Commenters in support of the proposal included a pesticide manufacturer organization and farmworker advocacy organizations. One public health organization supported the proposal, but recommended that the requirement be modeled after OSHA's confined space regulations, to include: Specific training for early entry, a requirement for workers to be provided respirators and other necessary PPE, written emergency rescue procedures and resources in case of an overexposure or other mishap, on-site monitoring of the worker from outside the entry zone, and recordkeeping of each entry.

Several agricultural producer organizations and pesticide manufacturer organizations supported the proposal, but expressed concern for the requirement for employers to manage heat stress.

EPA Response. EPA has decided not to amend the final rule based on OSHA's confined space regulations. OSHA's definition of a confined space is one in which there is limited or restricted means for entry or exit. These characteristics exacerbate any hazard to the employee, in that the employee could be overcome by a toxic atmosphere or by physical engulfment, such as in a grain storage bin, and be unable to quickly exit. EPA recognizes a similar potential for pesticide handlers making fumigant applications in greenhouses to be overcome by the fumigant. The WPS provides protections for such scenarios by requiring PPE, including respirators where required by the label, and continuous monitoring by a handler outside of the treatment area. The handler entering the greenhouse would have specific instructions on the labeled hazards. The monitoring handler must have access to the PPE required by the product labeling in case they would need to enter the greenhouse for rescue of the applicator. However, except for the use of fumigants, which have specific label requirements because of their increased potential for inhalation risk, the more common scenario of a worker entering a treated area on a farm, forest, or in a nursery during the REI would not pose such risks from a toxic atmosphere. It is unlikely that there would be an environment that could concentrate the pesticide and produce a potentially lifethreatening environment. The predominant component of exposure during work in a treated area where an REI is in effect is dermal, with rare exceptions. Specific information about the entry must include the human health hazards on the pesticide labeling, explanation of the required PPE and the proper way to wear and remove PPE, description of the tasks that may be performed and any limitations on the time permitted in the area. Workers directed to enter a treated area during the REI must have had the pesticide safety training so they may protect themselves. Employers must provide the PPE required by the product label for early entry to minimize exposure. Employers must provide early-entry workers with the decontamination supplies appropriate for pesticide handlers.

EPA agrees with commenters that heat stress can be a problem for workers in warm, humid climes and when employees must wear PPE. EPA notes that requirements related to heat stress for early-entry workers are already included in the existing rule at 40 CFR170.112(c)(6)(x) and 170.112(c)(7), and EPA did not receive comments to indicate this requirement has posed a problem for employers in the past so EPA has retained in the final rule the requirement for employers to take appropriate

measures to prevent heat-related illness.

<u>Comments in opposition to the early-entry exceptions</u>. A number of farmworker advocacy organizations voiced opposition, in general, to most or all of the early-entry exceptions in the existing rule, suggesting that workers should not be required to enter treated areas under an REI, due to risk of exposure.

<u>EPA Response</u>. In deciding whether to allow workers to enter treated areas prior to the expiration of the REI, EPA considered the risk to the workers and the benefits from the early-entry activities. In each case, EPA determined that the potential risks to properly trained and equipped early-entry workers are reasonable in comparison to the significant economic impacts from delaying necessary activities, provided that the required limitations to each exception are observed.

Comments on recordkeeping of oral notification. Several farmworker advocacy organizations supported the recordkeeping requirement, stating that the "proposed changes will ensure early entry workers are adequately informed about the risks of the work they are asked to do." In contrast, several states and their organizations expressed concern for the recordkeeping requirement, stating that it is not practical and would result in technical violations, such as failures to obtain the necessary signatures, without enhancing worker protection. The SBA Office of Advocacy also commented that the recordkeeping and retention schedule would present a burden to small businesses.

<u>EPA Response</u>. EPA was convinced by the rationale provided by the states and the SBA Office of Advocacy that the requirement for records of notification to early-entry workers was too burdensome for agriculture, while adding little or no protections for the workers. There is typically some urgency to the need for entry into a treated area while the REI is in effect; the added burden to create records during this time could be unreasonable as it would not necessarily increase protection of early-entry workers.

Comments on the use of the signal word to differentiate between handler and worker entry. One academic suggested that handlers, having higher risk from pesticide exposure because they are in close contact with the pesticide, should have separate re-entry intervals from workers.

EPA Response. EPA agrees that handlers may experience higher rates of exposure to pesticides as a result of their direct contact with the concentrated form of pesticides as they mix, load, and apply. As a result, handlers making application are often required to wear PPE for protection. In contrast, workers are most likely to have only dermal contact with the dried pesticides on the plants (although EPA's risk assessments also account for possibility pesticide may contact their eyes) owing to the risk management measures EPA imposes during the pesticide registration process; these include application rates, application methods, and REIs based on degradation of the pesticide. Accordingly, the only workers who should need to wear PPE are early-entry workers.

Comments on worker entry restrictions after applications. The commenter questions why EPA has established new REI requirements at § 170.107 of the proposed rule (in this final rule, the provisions appear at § 170.407(a) and (b)).

<u>EPA Response</u>. The REI requirements identified in § 170.407 are similar to those in the existing rule at § 170.112. The additional content of the requirement informs the reader that, in addition to the requirement that the employer must not allow or direct any worker to enter or remain in the treated area before the REI has expired, all treated area warning signs must be removed or covered before such entry is permitted, except for early entry under § 170.303. This clarifies the responsibility of the employer to ensure the posted information does not conflict with oral information.

<u>Comment on heat related requirements.</u> A commenter agreed with the requirement for protections of workers entering a treated area during an REI, but expressed concern for heat effects to

workers in PPE. The commenter went on to state that incidence of heat stress is dependent on the individual worker and their sensitivity to heat, and suggested that EPA acknowledge this subjectivity to avoid legal jeopardy for employers.

A state regulatory agency commented on the requirement for PPE, stating that is it reasonable to require the employer to provide the PPE, but the worker or handler may choose not to wear the PPE. This commenter stated that the rule should also hold the employee responsible for wearing PPE.

<u>EPA Response</u>. EPA agrees with commenters that heat stress can be a problem for workers in warm, humid climes and when employees must wear PPE. EPA notes that requirements related to heat stress for early entry workers are already included in the existing rule at 40 CFR 170.112(c)(6)(x) and 170.112(c)(7), and EPA did not receive comments to indicate this requirement has posed a problem for employers in the past so EPA has retained in the final rule the requirement for employers to take appropriate measures to prevent heat-related illness.

EPA disagrees with the comment that the rule should hold the worker responsible to wear PPE. The employer must ensure that the worker or handler wears the required PPE, and because the employer is making the pesticide use decision, the employer is responsible to ensure the required PPE is worn.

<u>Comment on information for workers</u>. A farm bureau representative agreed that workers should have appropriate information to protect themselves, but questioned why the worker would need to know what pesticide was used or which exception applied.

<u>EPA Response</u>. Should a pesticide exposure occur, response time may be critical if the employee is made ill. Informing the worker of the pesticide they may be exposed to may motivate the worker to take appropriate precautions, and could be critical information should the worker later require medical attention. Knowing the nature of the REI exception will help the worker understand the scope of the tasks permitted under the exception, and empower the worker to question work assignments that go beyond the scope of the particular exception.

B. Clarify Conditions of the "No Contact" Exception

- 1. Current rule and proposal. The existing WPS allows workers to enter areas while an REI is in effect for activities that do not result in contact with any treated surfaces. In the proposal, EPA sought to clarify the "no contact" requirement of the exception by explaining that performing tasks while wearing PPE does not qualify as "no contact." The proposal offered three examples of acceptable "no contact" activities.
- 2. Final rule. EPA has finalized the proposed clarification. The final rule adds to the exception the following language: "This exception does not allow workers to perform any activities that involve contact with treated surfaces even if workers are wearing personal protective equipment." The final regulatory text for this requirement is available at 40 CFR 170.603(a)(1).
 - 3. Comments and responses.

<u>Comments</u>. One farm bureau stated that workers are prevented from having contact with pesticides and their residues through the medium of PPE.

<u>EPA Response</u>. Although PPE – when properly fitted, worn, removed, cleaned and maintained – can provide significant protection against pesticide exposures, it does not eliminate exposure. The variation in exposure reduction offered by various types of PPE can be seen in EPA's "Exposure Surrogate Reference Table" (http://www.epa.gov/opp00001/science/handler-exposure-table.pdf). Use of PPE for activities involving contact with pesticide-treated surfaces does not reduce risks to the same level as no-contact activities. EPA has finalized the "no contact" exception as proposed because the PPE

appropriate for early entry into treated areas under this exception is appropriate only for activities that do not involve contact with treated surfaces.

<u>Comments on the exception</u>. One commenter stated that the exception cannot be considered to be "no contact" because the worker may be exposed from contaminated air or dust, and if they must dismount and repair the equipment they would be exposed to treated surfaces. The same commenter stated that restricting entry until 4 hours after the REI does not prevent harmful levels of exposure because pesticides continue to volatilize after application.

<u>EPA Response.</u> EPA believes that the commenter may have misunderstood the extent of the nocontact exemption. The no-contact exception does not presume that there is no risk of exposure; in recognition of those risks, early entry is only permitted subject to the protections required by § 170.605 (e.g., early-entry PPE, meeting the minimum age of at least 18 years old, access to decontamination supplies). The no-contact exception is limited to persons working in a treated area during the REI only if they will not contact, or be contacted by, pesticide residues from plants, from the soil or planting medium, water with residues, such as water from a drainage ditch, or pesticides that remain suspended in the air after application.

These conditions may be met by a worker performing tasks in a treated area after sprays, dusts, and vapors have settled out of the air, and the worker is:

- wearing footwear and is walking in aisles or on roads or paths through the treated area where
 plants or other treated surfaces cannot brush against the worker and cannot drop or drip
 pesticide on the worker, or
- 2. in an open-cab vehicle in a treated area where plants cannot brush against, or drop or drip pesticides onto the worker, or
- 3. in a treated area after an application that is incorporated or injected into the soil and the worker is not disrupting the soil surface, or
- 4. in an enclosed cab on a truck, tractor, or other vehicle.

Under the exception the worker may not enter the treated area if the pesticide is suspended in the air, and may not contact any treated surfaces.

C. Limit "Agricultural Emergency" Exception

1. Current rule and proposal. The existing WPS permits entry into a treated area during an REI when a state, tribal, or federal agency having jurisdiction declares the existence of conditions that could cause an agricultural emergency. EPA proposed that only agricultural emergency determinations by EPA, state and tribal pesticide regulatory agencies, and state departments of agriculture, could authorize early entry under the agricultural emergency exception.

In addition, EPA proposed to limit the time a worker may be in the treated area under the agricultural emergency exception when the label of the product used to treat the area requires both oral and written notification ("double notification"). Under the existing rule, there is no time limit; EPA proposed to establish allowing workers to be in a treated area under this exception for a maximum of 4 hours in any 24 hour period.

- 2. Final rule. EPA has finalized the proposal, with one change. The final rule does not include EPA as an agency with authorization to declare the existence of conditions that could cause an agricultural emergency because EPA decided that States and Tribes are best situated to decide what conditions in their respective jurisdictions could constitute an agricultural emergency. The final regulatory text for this requirement is available at 40 CFR 170.603(c).
 - 3. Comments and responses.

Comments on restricting the declaration of an agricultural emergency. One state supported the

proposal, but recommended broadening the declaration of an agricultural emergency to include the state governor. Another state found the proposal satisfactory. One grower organization opposed the proposal, stating that pre-approval to enter the treated area would be cumbersome and unnecessary if the criteria are clearly defined and documented. Another grower organization and a farm bureau from the same state expressed concern that this change would seriously impact growers' ability to enter a treated area to manage fires, fix broken irrigation and chemigation pipes, and address other problems that could pose risks to adjacent public areas and cause crop loss. These commenters recommended that EPA develop guidance to instruct relevant municipal agencies such as local fire departments to declare agricultural emergencies.

One department of agriculture stated that any entry into a treated area during the REI should be subject to the early-entry restrictions. This commenter stated that workers entering the area during an agricultural emergency exception should wear the PPE required by the labeling.

Commenters also suggested that there is a need for entities other than EPA, state departments of agriculture and the state pesticide regulatory agencies to declare agricultural emergencies. In the examples provided by commenters, fires and broken irrigation or chemigation pipes could pose risks to the public and the crop.

Two farm bureaus suggested that they did not receive specific information about the changes to the agricultural emergency exception and could not characterize its potential impact on producers. They recommended that EPA consult with state departments of agriculture and stakeholders to evaluate the impact and how the change would enhance worker safety.

<u>EPA Response</u>. As described in the preamble to the proposed rule, EPA noted that entities other than the state pesticide regulatory agencies, state departments of agriculture, and EPA might not have the background and technical expertise to assess the benefits and risks to workers from the entry while the REI is in effect, and might not understand the statutory requirement to consider both risks and benefits when establishing conditions for early-entry workers. EPA decided not to include state governors as an entity authorized to declare an agricultural emergency because it is not necessary; a state governor could direct the state department of agriculture or pesticide regulatory agency to determine whether conditions that could result in an agricultural emergency exist.

The need for pre-approval for conditions that may result in an agricultural emergency is a requirement in the existing rule. EPA has responded to the concern of the grower organization through its Interpretive Guidance Workgroup on the existing WPS, which clarified that state pesticide regulatory agencies may establish guidance or regulations describing the circumstances that could constitute an agricultural emergency and for which entry into areas under an REI is permitted. If a grower determines that such conditions exist at a site, then workers may enter the area while the REI is in effect under the agricultural emergency exception, consistent with applicable restrictions.

EPA has decided not to expand the declaring agencies to include municipal agencies such as local fire departments, but will work with state pesticide regulatory agencies and departments of agriculture to support the identification of circumstances that could constitute an agricultural emergency in their jurisdictions. EPA recommends that these entities identify, in their states, local conditions that could constitute such emergencies. Through state regulation or by policy, these agencies may pre-approve entry when such conditions occur.

EPA agrees with the department of agriculture that entry into a treated area during the REI must be subject to the early entry restrictions, and that workers must wear the PPE described on the label during their work periods.

Regarding the two responses suggesting that EPA consult with state regulatory agencies and

stakeholders, EPA believes the comment opportunity associated with publication of the proposed changes to the WPS addressed that need.

D. Codify "Limited Contact" and "Irrigation" Exceptions

1. Current rule and proposal. EPA established exceptions from the REI for certain limited contact and irrigation activities as administrative exceptions in 1995. Although these are noted in the existing rule at 40 CFR 170.112(e)(7), the terms and conditions of these exceptions are not included in the existing rule. These exceptions permit entry into a treated area under an REI for certain non-hand labor activities, including irrigation. The existing exception for irrigation requires, among other things, that the need for early entry be unforeseen.

EPA proposed to incorporate the terms and conditions for these exceptions into the final rule, and to eliminate the requirement for the need for irrigation to be unforeseen.

- 2. Final rule. EPA has finalized the rule as proposed. The final regulatory text for this requirement is available at 40 CFR 170.603(d).
 - 3. Comments and responses.

<u>Comments in support of the exceptions</u>. Two farm bureaus and a state department of agriculture specifically supported the codification of the limited contact and irrigation exceptions.

Comments in opposition to the exceptions. Two farmworker advocacy organizations expressed concern for codifying these exceptions, stating that improvements in training and establishment of an age restriction cannot adequately mitigate the risks. In addition, two such organizations opposed the relaxing of the early reentry restriction for irrigators, allowing early reentry even if the need for irrigation could have been foreseen before the pesticide application. They note that irrigators are at high risk of pesticide poisoning because they tend to work long hours and because they also often work alone with no coworker to assist in calling for help in case of pesticide or heat illness.

These commenters also noted that the rule requires that contact be limited to the feet, lower legs, hands, and forearms. They cited a California study of exposure to irrigators that indicated that nearly 33% of exposure occurred to torso and arms after the REI had expired. One farmworker advocacy organization urged EPA to prohibit early entry for all pesticide applications, given the high risks for applicators. They stated that early entry should be only for true agricultural emergencies. Concerns were also raised for the need for irrigation that is foreseeable, with comments suggesting that the employer needs to be aware of the risks and should consider managing the timetable for irrigation so workers can enter before the pesticide treatment.

EPA Response. EPA agrees that there is risk to workers from early entry, but believes that the new requirements of annual training and notification of the early entry that highlights the pesticides and risks from exposure, combined with the existing PPE requirements and activity limitations, will adequately protect workers in early-entry situations, including the limited contact and irrigation exceptions. Awareness of the limitations of the exception, for example, the number of hours and type of work the worker may perform, and requirements for PPE that are required, will help the worker recognize risks and takes steps to minimize them. EPA's general prohibition against early entry is expected to limit worker exposure during the REI. In granting the exception for irrigation, EPA has weighed the risk from exposure against the benefits of early entry irrigation and finds justification for the exception.

E. Eliminate the Option for an Exception Requiring Agency Approval

1. Current rule and proposal. Under the existing rule, an applicant may request approval from EPA for an exception to the prohibition on worker entry into a treated area during the REI for a specific need. EPA proposed to eliminate the process for requesting an exception from the rule.

- 2. Final rule. EPA is finalizing the proposal to eliminate the provision for exceptions requiring Agency approval.
 - 3. Comments and responses.

<u>Comment.</u> One grower opposed the elimination of the provision, citing the evolution of farming practices and the potential for conflict between new practices and the rule. The commenter stated that there is no administrative burden to the EPA, except to evaluate requests if they are submitted.

EPA Response. EPA included the administrative exception process into the WPS in 1992 in recognition that the general prohibition on routine early entry might significantly affect various agricultural entities or practices in ways that might only become apparent as the 1992 WPS was put into effect. EPA created a small number of exceptions during the 1990s, but none since 1997. The effects of reentry intervals on agricultural entities and practices are now sufficiently well understood that the administrative exception process is no longer needed in the WPS. As explained in the preamble to the proposed rule, EPA finds the pesticide re-evaluation process a more appropriate venue than the WPS for considering the economic impacts of REIs on particular agricultural entities and practices. Under EPA's registration review process, applicants may request alternative REIs for specific needs for their crop. This process takes into account the potential increased risk to workers and the benefits to the production of the crop. In cases where EPA finds that the revision of an REI is warranted, the product label will be amended to specify the REI for that particular use.

XII. Display of Pesticide Safety Information

A. Pesticide Safety Information Content

- 1. Current rule and proposal. The existing rule requires employers to display a pesticide safety poster containing the following information:
- Avoid getting on your skin or into your body any pesticides that may be on plants and soil, in irrigation water, or drifting from nearby applications.
 - Wash before eating, drinking, using chewing gum or tobacco, or using the toilet.
- Wear work clothing that protects the body from pesticide residues (long-sleeved shirts, long pants, shoes and socks, and a hat or scarf).
 - Wash/shower with soap and water, shampoo hair, and put on clean clothes after work.
 - Wash work clothes separately from other clothes before wearing them again.
- Wash immediately in the nearest clean water if pesticides are spilled or sprayed on the body. As soon as possible, shower, shampoo, and change into clean clothes.
 - Follow directions about keeping out of treated or restricted areas.
- There are federal rules to protect workers and handlers, including a requirement for safety training.

The existing rule also requires the employer to provide contact information for the nearest emergency medical care facility and to promptly update the safety information poster when any of the required contact information changes.

EPA proposed changing the term for what employers must display from "pesticide safety poster" to "pesticide safety information." EPA proposed retaining the existing content requirements of the existing rule, with one exception. EPA proposed removing the item regarding federal rules to allow the other information to be more prominent. EPA proposed retaining the requirement to display the contact information for the medical facility and amending the language from "nearest emergency medical care facility" to "a nearby operating medical facility." Finally, EPA proposed requiring the

employer to provide on the display the name, address, and telephone number of the state or tribal pesticide regulatory agency.

2. Final rule. EPA has finalized the proposed requirements for content, and has added a point to the proposed display requirements that advises workers and handlers to seek medical attention as soon as possible if they believe they have been made ill from pesticides. EPA has also amended one of the existing required points to clarify that if pesticides are spilled or sprayed on the body, workers and handlers should rinse immediately in the nearest clean water if more readily available than the decontamination supplies, and should wash with soap and water as soon as possible. The final rule refers to the requirement as "pesticide safety information" and allows display of the information in any format that meets the requirements of the rule, rather than only as a pesticide safety poster. EPA has included a requirement in the final rule for the employer to update the pesticide information display within 24 hours of notice of any changes to the medical facility or pesticide regulatory agency contact information. Finally, EPA has provided an option in the regulatory text that allows employers to comply by following the requirements at 40 CFR 170.311(a)(1)-(4) before they are fully implemented. The final regulatory text for these requirements is available at 40 CFR 170.311(a)(1)-(4).

The final rule delays implementation of the changes to the required pesticide safety information until two years after the rule is made final, in order to allow time for model pesticide safety information display materials to be developed and distributed.

3. Comments and responses.

<u>Comments.</u> Farmworker advocacy groups and public health organizations supported the emergency medical care change and inclusion of the state or tribal agency responsible for enforcement. However, they urged implementation sooner than the proposed two years from the effective date of the final rule. One commenter reported that a recent survey they conducted indicated that 25% of respondents did not complain about pesticide-related health problems or pesticide applications to the fields while they were working because they did not know to whom to complain and 62% feared losing their jobs if they were to complain.

In general, agricultural producer organizations, states and a pesticide registrant organization did not object to the proposed changes for providing emergency medical information but several commenters were concerned about spurious reporting of alleged violations resulting from inclusion of the state or tribal regulatory agency in the pesticide safety information. Commenters suggested that EPA should carefully monitor any reports of alleged violations and work with state and tribal agencies to monitor whether such reports are well-founded and whether the information is being used by others as a means of pursuing agendas unrelated to worker protection. Several commenters interpreted the proposal as requiring injured workers to contact state or tribal agencies responsible for enforcement for emergency medical attention. Several commenters requested that EPA state and clarify the purpose for posting the regulatory agency contact information (i.e., for worker protection). One state requested that EPA be less prescriptive of which agency contact information is provided because in some states, the lead agency for pesticide enforcement may have counterpart agencies that also enforce pesticide-related issues and jointly enforce the WPS.

A grower organization pointed out that the nearest operating medical facility might change depending on the time of day and wondered if the employer would need to list hours of operation and addresses of all emergency medical care facilities in the area where the employer operates.

One grower organization objected to including the regulatory contact information as part of the pesticide safety information display. One state argued that adding the regulatory agency contact

information to the poster would be redundant, because it is already available from many different sources, and impractical to implement at the state or employer level.

One commenter suggested the safety poster should always be in a standardized format and requested that EPA not allow the information to be displayed in several different formats.

Several commenters suggested that in addition to requiring the pesticide safety information display to contain information on the nearest medical facility, EPA should also require the display to include instructions for workers and handlers to notify their employer as well in the event of a medical emergency.

EPA Response. EPA has concluded that there was general support for the proposed requirement regarding the content of the safety information display, including the proposal to add contact information for the pesticide regulatory agency. EPA has delayed implementation of the final requirements for two years after publication of the final rule to allow time for display material to be updated, printed and distributed. However, EPA encourages employers to implement the new requirements prior to that date by allowing employers the option to use either the existing or the new safety information content prior to the implementation date.

In response to concerns about the placement of the medical facility information and the inclusion of regulatory agency information in the display, EPA has revised the regulatory text to clarify that the contact information about the medical facility must be clearly identified as the emergency medical contact information on the display. Further, the regulatory text separates the requirements to display the contact information for the medical facility and the contact information for the regulatory agency information. Displaying the regulatory agency information is important for the ability of workers and handlers to report possible violations, and in those states where it is already required, it does not appear to have generated spurious reporting of alleged violations. EPA appreciates that some states may already require employers to make such medical and regulatory information available and where state requirements meet or exceed the federal requirement, they do not need to be duplicated. However, EPA has added this requirement to the WPS to ensure the information is available to workers and handlers in all states.

EPA will work with states during and after implementation of the WPS to identify issues, including any problems with implementation of the revised pesticide safety information display requirements. EPA does not anticipate any systematic monitoring of reports of alleged violations, either to determine whether such reports are well-founded or whether the information is being used by others as a means of pursuing agendas unrelated to worker protection. If issues of abuse arise, EPA would anticipate working with the pertinent state or tribal regulatory agency as needed.

EPA disagrees with the request that the pesticide safety poster specify the purpose for providing contact information for the regulatory agency. Workers and handlers will receive training on the employer's responsibility to provide pesticide safety information and on how to report suspected pesticide use violations to the state or tribal agency responsible for pesticide enforcement (i.e., call the number on the pesticide safety information display). EPA believes including this information in the training for workers and handlers, rather than explaining on the display the rationale for including the regulatory contact information, balances the need to provide workers and handlers with contact information and the concerns of some stakeholders that providing this information will result in spurious and unnecessary calls to regulatory agencies.

EPA has not amended the final regulatory requirements in response to comments requesting that the regulation be less prescriptive in requiring the display to include contact information for the pesticide regulatory agency. The regulatory language does not specify that only a single agency

responsible for enforcement of the WPS must be included on the display; rather, it requires "[t]he name, address and telephone number of the State or Tribal pesticide regulatory agency." 40 CFR 170.311(a)(3)(x). EPA interprets this requirement to be flexible enough to allow the inclusion of information for multiple agencies when multiple agencies in the state are responsible for WPS-related regulatory activities.

EPA disagrees with commenters who asserted that it is unnecessary to include the regulatory agency contact information as part of the pesticide safety information display. While this information may be available from multiple sources within the state, it may not be readily accessible to workers and handlers. Workers and handlers receive training on reporting suspected violations and need to know where and how to find the contact information in order to do so. Including the regulatory agency contact information in a standard location, i.e., as part of the pesticide safety information display, ensures that workers and handlers will know where to look for this information if and when they need it.

EPA is finalizing the proposed requirement to identify a <u>nearby</u> operating emergency medical care facility to simplify the requirement in situations where the <u>nearest</u> operating emergency medical facility varies with the location of workers and handlers.

EPA disagrees with the comment requesting that the information be displayed in a standardized format. As long as the information is provided in a way that workers and handlers can understand, EPA sees no need to mandate a specific format.

EPA disagrees with the requests to include in the pesticide safety information display instructions for workers and handlers to notify their employer in the event of a medical emergency. Workers and handlers may notify their employer, and many may do so to request transportation for medical treatment or to report the incident. However, EPA has chosen not to include instructions to contact the employer as part of the safety display because in the event of an emergency, the most critical information for a worker or handler is the location of the nearest medical facility. EPA does not want to give workers and handlers the impression that they must delay seeking treatment to inform their employers that an incident has occurred.

B. Location of Pesticide Safety Information Display

- 1. Current rule and proposal. The existing rule requires agricultural and handler employers to display the pesticide safety poster at a central location on the establishment. EPA proposed to require that agricultural employers display the pesticide safety information at locations where decontamination supplies must be provided, in addition to the existing requirement to display it at a central location.
- 2. Final rule. In the final rule, EPA has amended the proposal to require that in addition to displaying pesticide safety information at a central location, employers must also display it at permanent decontamination supply locations and where decontamination supplies are provided in quantities to meet the needs of 11 or more workers or handlers. The final regulatory text for this requirement is available at 40 CFR 170.311(a)(5).
 - 3. Comments and responses.

Comments. Farmworker advocacy organizations and public health organizations supported requiring display of pesticide safety information where decontamination supplies are provided for easy access to safety information for farm workers and families at strategic locations. They asserted that this would improve the ability of farmworkers and their families to stay healthy. They maintained that due to language barriers, immigration status, and fear of retaliation, farmworkers are often reluctant to ask their employers for information. Three individual farmworkers also commented on the proposed rule and echoed concerns expressed by farmworker advocacy groups and public health organizations. The

commenters requested clear information in Spanish and English at a central location with easy access that includes telephone numbers, places to go for help, and hospitals in the area. They stated that it was important that employers give farmworkers the necessary information about the pesticide application without workers having to ask for information. About half of the grower organizations commenting had no objection to the additional mandate on employers and agreed that the additional reminders at decontamination sites have potential benefits. One farmworker advocacy organization recommended that EPA also require pesticide safety information to be displayed near where workers enter treated areas to remind workers to avoid coming into contact with pesticides before exposures occur.

Some grower organizations asserted that the proposed requirement would pose a significant burden. One commenter stated that duplicating the pesticide safety information at multiple sites throughout an agricultural organization did not equate to a better training program and believed this requirement would likely result in additional fines for noncompliance without raising safety awareness. To support the claim of additional burden without commensurate benefit, a commenter asserted that if a person views the same information in the same location repeatedly, he or she will soon disregard the information. Some grower organizations pointed out that workers are bused in for a day in the field and irrigators are sent to different areas by phone; none of these congregate at a central location.

Some grower organizations and a state supported only retaining the requirement to display pesticide information at the central display. A few grower organizations recommended that EPA allow for the pesticide safety information to be displayed either at a central location on the establishment or at decontamination sites. One grower organization recommended that EPA require that only emergency contact information, rather than the proposed pesticide safety information, be posted at decontamination sites.

One grower organization raised concerns with the requirement for the pesticide safety information display to be accessible when it is required to be posted, noting that it would be impractical and troublesome for workers to have 24-hour access to vehicles and equipment where pesticide safety information would be required to be displayed.

Many states opposed displaying the pesticide safety information at all decontamination sites. Because of the mobile nature of many decontamination sites, such as the back of a pickup truck, many noted the proposed requirement would be burdensome. One indicated that it would be difficult for a grower owning fields across multiple counties to keep the pesticide safety information accurate. States generally supported displaying the pesticide safety information at permanent decontamination sites and base of operation mix/load sites. Several states asked for clarification about what types of decontamination sites would be required to display the pesticide safety information. States suggested that permanent or fixed decontamination locations, such as portable toilet facilities and plumbed wash sites would be more appropriate locations for displaying the pesticide safety information than portable decontamination kits commonly carried by irrigation workers and others.

Other states mentioned the lack of protection from the weather of the pesticide safety information at OSHA-required restroom facilities and the lack of access to this information when the vehicles carrying decontamination supplies are locked up at night. Two states recommended different sizes for the pesticide safety information. One state suggested that pesticide safety information displays be no larger than 11×17 inches and laminated to withstand at least one year's worth of weather conditions for use at decontamination sites; this state also recommended resizing the existing pesticide safety information to 8.5×11 inches or less and made of durable card stock or plastic for the agricultural workers to take home. Another state recommended the safety sign be available in different sizes to accommodate displaying it at various sites.

One state recommended providing different pesticide safety information displays for workers and handlers, with information more specifically targeted to each audience. The commenter recommended that a handler safety display include primary instructions on how to remove pesticide-contaminated clothing, how to properly wash off pesticide residues in the eyes and skin, and what to do after these two processes are complete. Some states asserted that the poster is mainly targeted to workers.

EPA Response. EPA agrees with the commenters who supported requiring safety information displays at a central location and anywhere decontamination supplies must be provided because the information is a useful reminder of the hygienic safety principles from their training. However, EPA was persuaded by arguments that the burden to display the information at mobile decontamination sites could be substantial, based on concerns for their ability to display the information so that it could be easily seen by workers, such as by posting it on a vertical surface. The final rule requires employers to display the information at the central display and all permanent sites, including a lavatory or bathroom, where decontamination supplies are provided to meet the requirements of the rule. However, for other locations where decontamination supplies must be provided (certain non-permanent sites), the pesticide information display is required only when the supplies are provided for 11 or more workers or handlers. This aligns with OSHA's field sanitation standard that requires toilet facilities for 11 or more workers. EPA notes that employers may use these portable toilet facilities or permanent wash sites to display the information, as recommended by some states.

EPA disagrees that with the request to require pesticide safety information to be displayed near where workers enter treated areas. The final regulation, requiring the poster to be displayed at a central location, at permanent decontamination sites, and at sites where decontamination supplies are being provided for 11 or more employees, balances the burden on employers to post and maintain the display with the need to provide workers and handlers with pesticide safety information where supplies for addressing potential exposure are available. Workers and handlers receive training on the importance of preventing exposure. Requiring the pesticide safety information to be displayed at each entrance to treated areas would substantially increase the burden on employers to post and maintain the information that would not be outweighed by benefits to workers.

EPA does not agree with the contention that requiring the pesticide safety information display at multiple locations would result in fines for noncompliance without greatly benefiting the employee. The pesticide safety information display reinforces the hygienic training principles from the safety training, and when coupled with access to decontamination supplies, offers a hands-on opportunity for workers and handlers to adopt these practices. Additionally, information about medical facilities available to workers and handlers where they may be exposed to pesticides may help them take steps to respond to an emergency.

EPA disagrees with requests to require display of the pesticide safety information only at the central display or to offer the option to display it at either a central display or decontamination sites. Posting at decontamination sites is beneficial because the information would be readily available in an emergency, because EPA assumes many emergencies may involve some decontamination efforts. Having the display at the central location allows workers and handlers access to information such as the emergency medical assistance and regulatory agency contact numbers at the same place they can find information about pesticides recently applied on the establishment.

EPA disagrees with the request to require only emergency contact information, rather than the proposed pesticide safety information, to be posted at decontamination sites because the pesticide safety information provides helpful information to workers and handlers about washing after potential

exposure. Requiring this information at the site where supplies for decontamination are provided reminds workers and handlers about these hygienic practices at the point where they can take action.

In response to concern that requiring the pesticide safety information to be accessible could be impractical and troublesome, and might result in employers having to ensure that workers have 24-hour access to vehicles and equipment where pesticide safety information would be required to be displayed, EPA notes that the pesticide safety information must be displayed only "if workers or handlers are on the establishment and within the last 30 days a pesticide product has been used or a restricted-entry interval for such pesticide has been in effect on the establishment." 40 CFR 171.309(h). At times when no workers or handlers are on the establishment, the employer would not need to provide or ensure access to locations where the pesticide safety information is displayed. Further, the final rule requirement limits the locations where pesticide information must be displayed to the central location, permanent decontamination sites, and sites where decontamination supplies are being provided for 11 or more employees.

EPA appreciates the comments regarding display size and options for lamination. The final rule does not establish a specific size for the information or require it to be laminated. However, the final rule requires the information to be legible at all times while it is displayed, and EPA expects that employers will opt for the optimal size and protection from the elements for their specific needs. Because the final rule limits the type of decontamination sites covered by this requirement and includes flexibility for identifying the regulatory agency and a nearby operating emergency medical care facility, it is possible but unlikely that some growers with larger establishments may need to provide different specific contact information about the regulatory agency and/or the medical facility, depending on the area where workers or handlers are working.

Commenters suggested the information be available in English and Spanish. EPA notes that the requirement is for the information to be provided in a manner that the workers and handlers can understand, which may include making it available in English and Spanish, or in other languages as appropriate.

EPA plans to develop and make available to agricultural and handler employers posters bearing the pesticide safety information, in a bilingual and pictorial format and with space for employers to add the required regulatory agency and medical facility information. As discussed in the proposed rule, the information does not have to be displayed as a poster as long as the display includes the required information and meets the requirements of the section.

EPA disagrees with the commenter's request to provide different pesticide safety information displays for workers and handlers. The pesticide safety information display reminds workers and handlers about basic pesticide safety and hygienic principles that apply to both audiences. Developing and maintaining separate pesticide safety information displays for workers and handlers could result in a significantly higher burden on employers without providing substantial additional benefit to workers and handlers.

XIII. Decontamination

A. Clarify the Quantity of Water Required for Decontamination

1. Current rule and proposal. The existing rule requires employers to provide "enough water for routine washing and emergency eye flush" when workers are performing activities in areas where a pesticide was applied and the REI has expired. For early-entry workers, the existing WPS requires employers to provide "a sufficient amount of water" for decontamination. The existing WPS requires employers to provide handlers with "enough water for routine washing, for emergency eye flushing and

for washing the entire body in case of an emergency." EPA proposed to require specific quantities of water for workers, early-entry workers and handlers based on its 1993 guidance, "How to Comply with the Worker Protection Standard for Agricultural Pesticides; What Employers Need to Know." In the guidance, EPA recommended one gallon of water per worker for routine decontamination, three gallons of water for early-entry workers for decontamination and three gallons of water per handler for routine handwashing and potential emergency decontamination.

EPA requested comment on the proposed quantities of water and the use of waterless cleansing agents in place of soap, water, and single-use towels. EPA also requested information on the efficacy of waterless cleansing agents for removing pesticide residues.

2. Final rule. EPA has finalized the proposed decontamination water requirements. EPA has also clarified that employers must make the required quantities of water and other decontamination supplies available at the beginning of the work period. The final rule does not allow waterless cleansing agents to be used in place of water, soap, and single-use towels. The final regulatory text for these requirements is available at 40 CFR 170.411(b), 170.509(b) and 170.605(h).

3. Comments and responses.

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Comments. A majority of commenters supported the proposal to require one gallon of water per worker for routine decontamination, three gallons of water for early-entry workers for decontamination and three gallons of water per handler for routine washing and emergency decontamination, but many requested clarification of the time frame associated with the supply. They wondered if the prescribed amounts were the maximum quantity per site or per number of workers, the minimum amount at the beginning of the day or at all times during the work period. Of the 14 state pesticide regulatory agencies that commented, six supported the codification of the guidance to require that employers provide 1 gallon of water per worker for decontamination and 3 gallons of water per handler for routine washing and emergency decontamination. Eight agencies requested clarification of these quantities; they recommended that the quantity be indicated as the maximum per site or per number of workers; they also questioned whether the quantity was to be available at the beginning of the day, throughout the day, or at the end of the day. A state department of agriculture pointed out that requiring a change of clothing for workers will place a large burden on employers. Eight public health agencies and academics commented on the proposed specific quantities for workers and handlers. Two of the commenters recommended following the requirements in American National Standards Institute (ANSI) Z358.1-2009 while one recommended that EPA follow the OSHA requirements (29 CFR 1928.110) and the California field sanitation standards. One commenter did not believe water could remove oilbased pesticide products and would therefore not be effective for decontamination of oil-based pesticide products. Eight farmworker advocacy organizations expressed support for the proposed quantities of water but urged EPA opt for the stronger protections offered by OSHA and ANSI for workers and handlers. Of the seven growers and grower organizations, four were generally supportive but requested clarification of the time period in which the gallons per worker or handler would be required. Two grower organizations urged coordination with the OSHA requirements or adoption of the OSHA requirements. Only one grower organization believed that it was a mistake to specify quantities of water for workers and handlers. Of the five farm bureaus that commented, four did not support the proposed quantities of water; these four supported maintaining the existing rule requirements. Some of the reasons the commenters included: a large number of workers would mean an impractical amount of water; the existing language on a "sufficient" amount of water adequately addresses this problem; and a "specific amount of water may re-direct compliance from actions that are clearly focused on worker safety to merely technical considerations." One farm bureau understood the proposal to be clarification

and codification of existing compliance expectations. A pesticide manufacturer organization commented that the quantities were reasonable but prescriptive. This commenter requested clarification about the time period for the water requirements; as an example, the commenter wondered whether the water for handlers would be required at the beginning of the day or at all times. An agricultural organization was supportive and agreed with EPA that it is important to have proper decontamination supplies available. Two other organizations recommended that EPA incorporate the ANSI/OSHA standards.

Two farmworker advocacy organizations, one public health organization, one farm bureau, one pesticide manufacturing organization and one grower organization commented on whether waterless cleansing agents should be used in place of soap, water, and single-use towels to remove pesticide residues. Two commenters did not support replacing soap and water with the waterless cleansing agents; they stated that alcohol- and chemical-based waterless cleansing agents were designed to kill bacteria and not remove pesticide residues. Waterless wipes designed to remove dirt and grime were also not an acceptable substitute for soap and plenty of clean water. The remaining commenters were in favor of using the waterless cleansing agents. One commenter felt it would be reasonable for routine worker decontamination but not practical for handler decontamination. Two commenters requested that EPA evaluate the use of such agents, but did not provide any data on the efficacy of these agents to assist in the evaluation. Only one commenter argued for use of the waterless cleansing agent if it was a neutralizer. This particular commenter provided a reference indicating that Reactive Skin Decontamination Lotion (RSDL©) would be effective against organophosphates.

EPA Response. EPA notes that the proposed quantities of water for decontamination are intended for agricultural settings that are not subject to the field standards of OSHA and ANSI. The WPS requirements are meant to be protective, flexible and not overly burdensome in agricultural settings where OSHA's field sanitations do not apply. In the final rule EPA is requiring a minimum of 1 gallon of water per worker and a minimum of 3 gallons of water per handler. Based on comments, EPA has clarified that the specified amount of supplies be available at the beginning of the work period and that they are to be calculated per worker and per handler. The final rule does not require the replenishment of used supplies until the beginning of the next work period. As for the comment that water would not remove oil-based pesticide products, that is why the rule requires soap be provided with the decontamination supplies. The use of soap and water as a first response measure in the field should help remove enough of these pesticides to provide some immediate removal and protection from exposure before accessing more effective decontamination measures that may be more protective. EPA acknowledges the proposed requirement for a change of clothing for workers was inadvertently included in the proposed regulatory text and that was a mistake so it has been removed in the final rule.

The information supplied by commenters was insufficient to convince EPA to replace water, soap, and single-use towels with a waterless cleansing agent. The reference provided for one waterless cleansing agent was useful but not a practical solution because it appeared it would only be effective against organophosphate pesticides, so this particular agent would be of limited use. Workers and handlers are likely to encounter more than one family of pesticides in their work, so water and soap would still be necessary for other pesticides. Therefore, EPA is requiring in the final rule that the employer supply water, soap, and single use towels in quantities sufficient to meet the worker's and handler's needs. Hand sanitizing gels and liquids or wet towelettes do not meet the requirement for single-use towels.

B. Eliminate the Substitution of Natural Waters for Decontamination Supplies

- 1. Current rule and proposal. For sites where worker or handler activities are farther than one-quarter mile from the nearest vehicular access, the existing rule permits employers to allow workers and handlers to use clean water from springs, streams, lakes or other sources ("natural waters" for the purposes of this section) for decontamination, if such water is more accessible than the employer-provided water. The employer must ensure any water used for decontamination, including natural waters, is of a quality and temperature that will not cause illness or injury. EPA proposed to eliminate the provision that allows employers to permit workers and handlers to substitute natural waters for the required decontamination supplies at remote sites. For remote sites, the proposal would have maintained the existing requirement for employers to provide all decontamination supplies (soap, single-use towels, clean change of clothing and water) at the nearest point of vehicular access. However, the existing regulation does not permit substitution of waters from natural sources for the decontamination water at the point of nearest vehicular access, and EPA's proposed change mischaracterized the existing requirements.
- 2. Final rule. In the final rule, EPA has removed from the regulatory text the provision that allows employers to permit workers and handlers to use clean water from springs, streams, lakes or other sources if that water is more accessible in remote locations where the decontamination supplies are farther than one-quarter mile from where workers and handlers are working. EPA is taking this approach to remove confusion about the employer's responsibilities. The employer must always provide the decontamination supplies in quantities outlined in the regulation. When workers or handlers are performing tasks at remote sites more than one-quarter mile from the nearest point of vehicular access, employers must provide all required decontamination supplies (soap, single-use towels, and water, plus clean change of clothing if required) at the nearest point of vehicular access. Under the final rule, employers are required to make the decontamination supplies available as close as possible to the remote site (as determined by how close a vehicle can get) and employers do not have to check or confirm that water from springs, streams, lakes or other sources at remote sites meets the standard of being of a quality and temperature that will not cause illness or injury. EPA has amended the training requirements to cover the proper use of natural waters at remote sites by workers and handlers. EPA believes that workers and handlers in these remote areas should primarily rely on the decontamination water that is provided by the employer for routine washing and emergency decontamination because the quality of the natural waters at the remote site is unknown. In case of an overexposure, such as a spill, contact from drift, or direct spray, workers and handlers should always use the emergency decontamination supplies if they are more readily available. However, training will emphasize that workers or handlers should rinse immediately using the nearest source of clean water to mitigate the exposure, and to use the nearest source of clean water, including springs, streams, lakes or other sources, if more readily available than the decontamination supplies. Workers and handlers will be advised through training that as soon as possible they should decontaminate thoroughly with the soap, water and towels provided by the employer and, if available, change into clean clothes. EPA plans to modify training materials to incorporate this information. The final regulatory text for worker and handler decontamination is available at 40 CFR 170.411(d), 170.509(c), and 170.605(h)-(i).

3. Comments and responses.

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<u>Comments</u>. Many commenters supported not using natural waters to replace the required decontamination supplies. Several commenters also supported the need for employees to access the nearest clean water in case of an emergency or significant exposure. Seven state pesticide regulatory agencies commented on the proposal. Two of the agencies said they would support the proposal if use of the natural waters were allowed for emergency decontamination. Five agencies supported the

proposal but commented that the term "natural waters" was confusing; they suggested replacing the term with "water of a quality and temperature that will not cause further injury." One agency felt the proposal complicated matters without a clear benefit. Three public health organizations and academics supported the proposal. One suggested that the use of natural waters for decontamination should be managed without letting the pesticides enter public waters. Another commenter suggested that in a true emergency, it was important to use whatever water was available. Two farmworker advocacy organizations supported the proposal to eliminate the exemption allowing employers to use natural bodies of water in place of the required decontamination supplies. They suggested that the actual cleanliness of the natural bodies of water was unknown and expressed concern that the quality of the natural waters might be questionable and not the best choice for decontamination. Of the four growers and grower organizations that commented, three did not support the proposal. One commenter said the use of natural waters should be reserved for true emergency situations; for immediate decontamination, the employee should use whatever water is available. Three farm bureaus commenting on this proposal did not support the proposal and urged EPA to discard it. One farm bureau suggested that employees be allowed to use natural water bodies to supplement needs in the event of an emergency. Finally, one farm bureau commenter stated that large scale planting activities can place workers more than one-quarter mile from vehicular access, and retaining the existing requirement is more reasonable than expecting workers to carry washing water with them.

EPA Response. EPA maintains its position that the employer-provided decontamination supplies, provided within one-quarter mile of the workers and handlers — or in remote areas, at the nearest point of vehicular access to worker and handler work sites — are the appropriate supplies for routine washing and emergency decontamination. The employer must ensure this water meets the minimum criteria for quality. However, EPA agrees with commenters that prompt washing in clean water is an important step in reducing overexposure, for example, from a spill, contact from drift, or direct spray. EPA has identified acute incidents that would have been mitigated if the exposed worker or handler had decontaminated promptly. EPA is concerned that the existing requirements for employers to ensure the quality of natural waters prior to their use and for employers to specifically permit the use of natural waters will prevent workers and handlers from using these waters to decontaminate in case of an emergency. Ensuring the quality of all natural waters on their establishment could be burdensome for employers, and as a result they might not evaluate the quality or permit the use of natural waters.

To ensure that workers and handlers needing emergency decontamination can use water that is more accessible than the decontamination water provided by the employer, the rule permits the use of natural waters for emergency decontamination by not prohibiting the use of such waters by workers and handlers. The employer is not required to predetermine that the quality of such water meets the criteria for the rule since it is not provided as the water for decontamination supplies, but is merely available for their employees to access in an emergency situation. The employer is still required to supply separate water for decontamination and to assure that the quality of the supplied water meets the criteria of the rule. Workers and handlers seeking to mitigate an emergency exposure will be informed in their training to use the nearest clean water to immediately rinse off if such water is more readily available than the employer-provided decontamination supplies, and then go to where the employer-provided supplies are to fully decontaminate. EPA believes the benefits of using natural clean waters to decontaminate immediately in an emergency pesticide exposure situation outweighs the potential risks of making workers or handlers wait until they can use supplied decontamination water that has been evaluated for quality but may be less available to immediately address the exposure.

Although the quality of the natural waters is unknown, EPA thinks that washing in natural waters in any agricultural area is unlikely to pose risks comparable to a significant direct pesticide exposure.

C. Requirements for Ocular Decontamination in Case of Exposed Pesticide Handlers

- 1. Current rule and proposal. The existing rule requires employers to provide "enough" water to handlers for routine and emergency washing and emergency eye flushing. For handlers who use products that require eye protection, employers must provide each handler with at least one pint of water that they can carry for use in the event of an ocular pesticide exposure. EPA proposed to require employers to provide clean, running water at permanent (i.e., plumbed and not portable) mixing and loading sites for handlers to use in the event of an ocular pesticide exposure when using a pesticide with labeling that requires eye protection.
- 2. Final rule. Under the final rule, employers must provide water for ocular decontamination either through a system capable of delivering 0.4 gallons/minute for at least 15 minutes or from six gallons of water able to flow gently for about 15 minutes. This water must be available at all mixing and loading sites where handlers are mixing or loading a product that requires eye protection or when closed systems, operating under pressure, are in use. The final rule amends the existing requirement for employers to provide at least one pint of water per handler in portable containers that are immediately available to handlers applying the pesticide, rather than to all handlers mixing, loading and applying pesticides, if the pesticide labeling requires protective eyewear. The final regulatory text for these requirements is available at 40 CFR 170.509(i).

The term "potable" in the preamble and regulatory text for the proposed rule was a typographical error and has been corrected to "portable" in the final rule.

3. Comments and responses.

Comments. There was general support for this proposal. Nine state pesticide regulatory agencies supported the proposal but several requested definitions or clarifications and some supported the proposal conditionally only if EPA allowed for certain types of water tanks. One pesticide manufacturing organization stated the proposal was reasonable with certain understandings such as if the water does not have to be potable, employers would be allowed 12 months to provide the eye decontamination station, it was required only for permanent mixing/loading sites which already had running water, and no recordkeeping of the water flows would be required. All four public health organizations and academics that commented supported the proposal, saying it was "reasonable." However, they urged the adoption of the other ANSI requirements which included an emergency eyewash and shower equipment capable of delivering 20 gallons per minute for 15 minutes. Seven farmworker advocacy organizations commented they supported the requirement for ocular decontamination of exposed handlers. All five farm bureaus commenting on the proposal generally supported it. Four of the farm bureaus urged EPA to ensure that the "availability of potable water for decontamination requirements apply only to permanent mixing and loading facilities."

Many commenters from across all groups urged EPA to adopt or coordinate with ANSI standard Z358.1-2009 and/or the OSHA requirements, 29 CFR 1928.110, as several states have done. Another commenter felt the proposal was reasonable but EPA should follow the ANSI guidelines because running water was not enough for ocular decontamination. The commenter noted that a faucet cannot be turned on in one second or less, operated hands-free, or allow the injured person to hold eyes open and have automatically tepid water flow. They said ANSI should be followed because it requires portable gravity-fed eyewashes and portable pressurized eyewash/drench hose units and both keep the fluid uncontaminated and portable.

Several commenters from across multiple groups requested a definition of "permanent mixing and loading site" and "a system capable," and some state pesticide agencies suggested EPA use "plumbed mixing and loading site" instead of "permanent mixing and loading site." Two grower organizations pointed out that permanent mixing and loading water sources are clean but not necessarily potable; many remote locations without permanent plumbing have no potable water because nursery and tree farm locations use ponds or reservoirs as their source of water.

Several commenters from state pesticide regulatory agencies, grower organizations and farm bureaus questioned whether the final rule included "nurse rigs," "nurse tanks" and "gravity-fed tanks" or similar types of water storage tanks, and many said they supported the proposal based on the final rule permitting the inclusion of such sources as allowable sources of the water for eyeflush since many permanent mixing and loading sites did not have running water but instead relied on these other types of water sources. The commenters explained that much of the mixing and loading is done in the field rather than at site with running water so it was important to be able to use this water for eyeflush to minimize burden. One commenter pointed out that recharging a simple eyewash deluge station for occasional use with 6 gallons of water, the proposed requirement, would not result in a significant expenditure or additional labor. Other commenters wondered if the water for decontamination needed to be potable.

EPA Response. The OSHA standard at 29 CFR 1910.151(c) specifies that "... where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided ..." The ANSI standard provides specifications for two types of eyewash stations, plumbed and gravity-fed. The specifications describe a system with a precise rate of flow (0.4 gallons/minute for 15 minutes), that can activate in 1 second or less and does not require the user to control the flow of water. While the OSHA and ANSI standards are very protective, EPA believes that it would be very costly and burdensome for employers to provide eyewash systems that meet the OHSA and ANSI standards given the remote sites often encountered with mixing/loading sites and agricultural operations and settings. The final rule requirements provide handlers with mitigation appropriate to pesticide exposure in agricultural settings at significantly lower costs than the ANSI standards.

Based on the comments, EPA realized that there might have been some confusion regarding the nature of permanent mixing and loading sites, the plumbing associated with both permanent and nonpermanent mixing and loading sites, and the quality of the water required. EPA proposed to require eyewash systems only for permanent mixing and loading sites since EPA believed it was common for most "permanent" mix/load sites to have running water and therefore it would be relatively easy to provide eyewash systems that could meet the desired flow rate and standard. EPA received comments indicating that was not the case. Therefore, in the final rule, EPA decided to apply the requirements for eyewash systems to all mixing and loading sites where pesticides whose labeling requires protective eyewear are handled because the risk to handlers who mix and load these products is the same, regardless of whether they perform the mixing/loading tasks at a permanent site or a mobile site. Additionally, rather than specify that eyeflush water must be running water and what types of water tanks or eye wash systems would comply with the requirement, EPA opted for flexibility. The final rule allows employers to provide either at least 6 gallons of water in containers suitable for providing a gentle eye flush for about 15 minutes, or a system capable of delivering gently running water at a rate of 0.4 gallons per minute for at least 15 minutes to satisfy the requirement. EPA did not propose recordkeeping of the water flows and there is no such requirement in the final rule. One emergency eyewash system is required at each mixing/loading site where a handler is mixing or loading a product

whose labeling requires protective eyewear for handlers, regardless of how many handlers are mixing or loading at that site. Lastly, the final rule retains the existing requirement for water to be of "a quality and temperature that will not cause illness or injury." EPA did not propose to require "potable water" for the eyeflush water as some commenters indicated, and there is no requirement in the final rule for eyeflush water to be potable water, although the employer must ensure that it is of a quality and temperature that will not cause illness or injury when it contacts the skin or eyes or if it is swallowed. *D. Showers for Handler Decontamination*

- 1. Current rule and proposal. The existing rule establishes specific requirements for routine and emergency handler decontamination supplies, but these requirements do not include shower facilities. EPA considered but did not propose a requirement for handler employers to provide shower facilities.
- 2. Final rule. EPA has not included in the final rule a requirement for employers to provide shower facilities for handlers.
 - 3. Comments and responses.

Comments. Many commenters from growers and grower organizations, farm bureaus and agricultural organizations supported the proposal's omission of a provision requiring shower facilities for handlers. They cited prohibitive costs and burden, and noted the provision would not necessarily guarantee use, and therefore would not guarantee any reduction in take-home or handler exposure. One state pesticide regulatory agency detailed its experiences after 10-15 years of shower use in agricultural settings in the state and noted that their inspections revealed that showers were "largely unused." Several commenters from public health organizations, academia and farmworker advocacy organizations requested that EPA require employers to provide shower facilities for handlers, and said such facilities are important for emergency eyewash and decontamination. Those supporting a requirement for shower facilities indicated that handlers would use them if they were provided, especially with better training about the importance of using showers and reducing take-home pesticide exposure. Worker advocacy organizations also thought showers should be provided for workers. Commenters from both groups generally agreed that better training and adequate information on reducing take-home exposure, as suggested by EPA, is needed. Several commenters from across both groups said improved training would be a better, more reliable approach to addressing how to reduce take home exposure.

<u>EPA Response.</u> EPA agrees that the potential cost and burden of providing showers for handlers as described in the proposal, combined with the lack of confidence that most handlers would routinely use showers if provided, led to the conclusion that a shower requirement would be unlikely to reduce risks to an extent commensurate with the costs. EPA also believes that the additional training being required for handlers, combined with clarified decontamination provisions such as the provision of at least 3 gallons of water per handler for routine and emergency washing, will reduce take-home exposure without requiring shower facilities. EPA also believes the new requirements for eyewash systems will address concerns raised about the need for shower facilities to provide for eyewash in ocular exposure emergencies.

XIV. Emergency Assistance

A. Current rule and proposal. The existing WPS requires employers of workers or handlers, including those handlers employed by the agricultural establishment or those working for a pesticide handling establishment, to provide prompt transportation to an emergency medical facility to employees who have been poisoned or injured by exposure to pesticides used on the establishment. Emergency medical assistance under the existing rule consists of the prompt provision of transportation to an emergency medical facility for the worker or handler and the provision of obtainable information

about the exposure, including information about the product(s) that may have been used, to emergency medical personnel or the exposed employee.

EPA proposed to require agricultural and handler employers to provide emergency medical assistance within 30 minutes after learning that an employee may have been poisoned or injured by exposure to pesticides as a result of his or her employment, replacing the current standard of "prompt." The proposed change was intended to ensure that the potentially injured party would be on route to a medical facility within 30 minutes.

EPA also proposed that the employer provide a copy of the pesticide label, or specific information from the label, along with the SDS and circumstances of the pesticide use and potential exposure, to employees potentially injured by exposure to pesticides and to treating medical personnel.

B. Final rule. EPA has retained the existing requirement for providing transportation and information promptly. The final rule clarifies that these requirements apply only to current or recently employed workers, and that emergency assistance must be provided if there is reason to believe that a worker or handler has been potentially exposed to pesticides or shows symptoms of pesticide exposure.

EPA has amended the requirement for the information that the employer must provide related to emergency assistance. The final rule requires the employer to provide to treating medical personnel a copy of the SDS, product name, EPA registration number and active ingredient for each pesticide product to which the person may have been exposed, as well as the circumstances of application or use of the pesticide on the agricultural establishment and the circumstances that could have resulted in exposure to the pesticide. This is a slight change to the existing rule which makes the information available to the worker or handler. In this final rule, the worker or handler has access to the information through the hazard communications requirement. This provision deals specifically with meeting the needs for medical assistance, and requires that the information be provided to the medical personnel.

EPA has clarified in the final rule that the provision of the emergency assistance requirement for transportation and information applies only to currently employed workers seeking emergency medical assistance or recently employed workers within 72 hours after their employment for acute exposures occurring on the agricultural establishment.

Readiness is among the most important factors in an employer's ability to promptly carry out the emergency assistance requirements. EPA strongly encourages employers to develop an emergency response plan and to address in such a plan details related to the emergency medical assistance requirements of the WPS. EPA also encourages employers to periodically test, evaluate and, if necessary, update the plan. EPA will develop a sample plan to help employers prepare for possible pesticide-related emergencies. Employers can also find additional information concerning the development and implementation of an emergency preparedness program at the U.S. Department of Homeland Security's web site, http://www.ready.gov/business/.

Although EPA believes that it is important for employers to develop emergency response plans, EPA has not made this a requirement of the final rule. EPA recognizes that pesticide exposure is just one of many hazards that should be addressed in an emergency response plan, and that EPA has very little information about the extent of emergency planning in the agricultural community. Accordingly, EPA has decided that it would be unwise to address this issue in the WPS without the benefit of a more robust dialogue with all stakeholders.

The final regulatory text for these requirements is available at 40 CFR 170.309(f) and 170.313(k).

C. Comments and responses.

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Comments. Many private citizens and farmworker advocacy organizations, some pesticide state regulatory agencies and several public health organizations supported the proposal to require

agricultural employers and handler employers to provide emergency medical assistance within 30 minutes after learning that an employee may have been poisoned or injured by exposure to pesticides as a result of his or her employment, replacing the current standard of "prompt." They stated that the clarification of time for the provision of transportation and information would improve the safety of farmworkers.

Many farmworker advocacy organizations, academic institutions, public health organizations and another organization expressed concern that the proposed emergency response time of 30 minutes is too long and recommended that it should be further reduced. Commenters reasoned that pesticide poisoning can be fatal or result in long-term effects if not quickly treated.

On the other hand, many commenters, mostly growers and farm bureaus, and some states and agricultural producer organizations expressed opposition to the proposal and favored retaining "prompt" to allow more flexibility due to geographical constraints. The SBA Office of Advocacy stated that small farms that are farther away from medical facilities would not be able to obtain emergency transportation within the timeframe. Those with few employees and limited transportation options would be overburdened in attempting to comply with a 30 minute timeframe. Commenters representing many states, several agricultural industries, many growers and farm bureaus, and the SBA Office of Advocacy recommended that emergency response requirements should apply only to current employees seeking emergency medical assistance for acute incidents.

Additional comments from states and their organizations recommended that the agriculture emergency requirement address only acute exposures to current employees of the establishment. They raised concerns for the potential for former employees or those with exposures in the past to request emergency assistance. One commenter stated that allowing any person who was ever employed by the establishment the ability to demand emergency assistance could cause problems with compliance and enforcement. Some of these organizations, including grower organizations claimed that the current definition for "poison or injured" is vague and could cause agricultural employers to be required to provide emergency assistance for minor health issues that may not be pesticide related. They also requested clarification of the term "emergency medical facility."

The grower and agricultural industry commenters expressed concern with the "proposed provisions and interpreted the proposal as requiring injured workers to contact state lead pesticide agencies responsible for enforcement for emergency medical attention. They stated that the proper reaction to an incident remains the responsibility of the employer who can best respond to the needs of their employees in a timely fashion. Commenters also recommended that the requirement allow, similar to OSHA, trained first aid providers on the establishment to provide care, which could enable more timely treatment.

Commenters noted that requiring the employer to provide the label to employees potentially injured by exposure to pesticides and to treating medical personnel could lead to further exposure, if the employee takes an open container of pesticides bearing the label. Further, commenters suggested that the information outlined in the proposal could be obtained from sources other than the label.

<u>EPA Response.</u> EPA was convinced by the concerns raised by members of the agricultural community that geographical constraints, in some cases, would make the 30 minute response timeframe for transportation difficult or impossible to meet. Agricultural establishments can be very large and are often distant from population centers. Remote locations, including those in forestry, are common; and the distance to an emergency medical facility or to an ambulance service can be significant.

The final rule requires employers to comply with the emergency assistance requirements by promptly making transportation available to an emergency medical facility for potentially injured employees and providing the SDS, specific product information, and information about the exposure to the treating medical personnel. Because the information about the pesticide may be critical to effectively manage the illness, EPA decided to focus the requirement to ensure that treating medical personnel receive the information. The agricultural employer must provide that information in a way that is reasonably expected to be accessible to the treating medical personnel. The requirement does not preclude the employer providing the information to injured employees and does not prevent injured employees from requesting this information. This requirement will allow continued flexibility for employers and encourage timely medical treatment for potentially injured employees.

In deciding to retain the requirement for prompt provision of transportation, EPA also took into consideration OSHA's standard for the provision of transportation to persons in construction, which requires "Proper equipment for prompt transportation of the injured person to a physician or hospital." 29 CFR 1926.50(e).

EPA agrees with the recommendation to clarify that the requirement applies only to current or recently employed workers seeking emergency medical assistance for acute exposures occurred at the agricultural establishment, and has revised the final rule accordingly. The final regulation also addresses the comment regarding the vagueness of "poisoned or injured person" and clarifies that emergency assistance must be provided to "a worker or handler that has been potentially exposed to pesticides or shows symptoms of pesticide exposure as a result of his or her employment." In response to the requests for language clarifications, EPA notes that a hospital, clinic, or infirmary offering emergency health services qualifies as an emergency medical facility for purposes of the WPS. EPA notes that for some cases of suspected pesticide injury, the attention of a trained first aid provider can mitigate the injury. Such treatment would not negate the obligations of the employer to provide transportation promptly to an injured employee, or to provide information about the pesticide and exposure to medical personnel, but is encouraged. Allowing a competent first aid provider to administer timely treatment to an injured employee could offset complications from longer exposures.

EPA agrees with comments that a requirement to provide the label in the event of an emergency could be burdensome and place employees at risk for additional exposure if the label is attached to an open container of pesticides. EPA has not included the proposed requirement to provide the label or information from the label; rather, the final rule requires the employer to provide the necessary information, but does not specify the source of the information. EPA has removed from the list of specific pieces of information the employer must provide information about antidote, first aid, and recommended treatment because the SDS contains this information. EPA notes that the information about the product and the SDS will be available as part of the pesticide application and hazard information.

Finally, the employer must provide information about the pesticide and the exposure to the treating medical personnel.

XV. Personal Protective Equipment

A. Respirators: Fit Testing, Training and Medical Evaluation

1. Current rule and proposal. The existing regulation requires handler employers to ensure that each handler's respirator fits correctly. However, the existing rule does not provide specific details on ensuring that a respirator fits properly, nor does it require employers to conduct medical evaluations of the handler's fitness for respirator use, provide training on the proper use of respirators, or retain fit test records.

EPA proposed to require handler employers to comply with the respirator fit testing, training, and medical evaluation requirements set by OSHA at 29 CFR 1910.134 whenever a respirator other than a dust or mist filtering mask is required by the labeling. EPA did not propose any new requirements for filtering facepiece respirators (OSHA's term for dust or mist filtering masks). The OSHA standard includes a specific standard for fitting a user for respirator use, training on recognizing when the respirator seal may be broken, and what steps to take to properly use and maintain respirators. OSHA also requires respirator users to be medically evaluated to ensure the respirator use does not cause undue stress on their bodies. EPA proposed to require that employers comply with the OSHA requirements for fit testing, training, and medical evaluation by cross-referencing 29 CFR 1910.134, in order to avoid creating a duplicative regulation and to ensure that if technology advances lead OSHA to amend its standard, the change would automatically apply to pesticide uses subject to the WPS as well. EPA also proposed to require handler employers to maintain records of the fit test, training, and medical evaluation for two years.

2. Final rule. EPA has retained the proposed elements in the final rule, with some changes and clarifications. Specifically, the final rule cross references and requires compliance with the OSHA standards for fit testing, training, and medical evaluation when a respirator is required by the labeling. The final rule expands from the proposal the types of respirators covered by the requirement to include filtering facepiece respirators. The final rule also adds an additional item to the list of conditions that would trigger replacement of the gas- or vapor-removing canisters or cartridges.

In the final rule, EPA has retained the proposed requirement for handler employers to maintain records of the fit testing, medical evaluation, and training. The final rule clarifies that the required training is limited to the care and use of respirators, 29 CFR 1910.134(k)(1)(i)-(vi), and does not include the training on the general requirements (i.e., 29 CFR 1930.134(k)(1)(vii)).

The final regulatory text for these requirements is available at 40 CFR 170.507(b)(10) and 170.507(d)(7).

3. Comments and responses.

<u>Comments – support.</u> EPA received many comments in favor of requiring handler employers to comply with the respirator fit testing, training, and medical evaluation requirements established in the OSHA standard. Many farmworker advocacy organizations and some PPE manufacturers asserted that EPA should also apply the proposed standards for fit testing, training, and medical monitoring to users of filtering facepiece respirators in addition to the other respirator types (e.g., tight fitting elastomeric facepieces). Commenters suggested that filtering facepiece respirators are widely used and covered by OSHA's respirator requirements, and that their exclusion would result in inadequate protection for many pesticide handlers. One state department of agriculture expressed support for the adoption of OSHA respiratory standards with the exception of the recordkeeping requirement.

EPA Response. In the final rule, EPA has required that employers comply with the respirator fit testing, training, and medical evaluation requirements described in the proposed rule when the use of respirators is required by the labeling. The final rule also expands its coverage to include filtering facepiece respirators (referred to as dust/mist filtering respirators in the proposal). EPA included filtering facepiece respirators in the final rule to ensure that handlers required to use any type of respirator are adequately protected. Filtering facepiece respirators need to be fit tested and used properly to provide the intended protection. In addition, this will ensure that respirators used under the WPS provide the same level of protection as comparable respirators used under OSHA's respiratory protection requirements. EPA does not believe that the recordkeeping requirement for employers impose unnecessary burden in comparison with the benefits.

Comments - adopt full OSHA respiratory protection program. Many farmworker advocacy organizations stated that EPA should require compliance with all elements of 29 CFR 1910.134, rather than the proposal to just include fit testing, training, and medical evaluation. Specifically, they urged EPA to adopt OSHA's requirements for employers to develop a respiratory protection program (29 CFR 1910.134(c)) and conduct a workplace hazard evaluation (29 CFR 1910.134(d)(1)(iii)).

EPA Response. EPA acknowledges that, if the final rule were to require handler employers to comply with the OSHA requirement to adopt a worksite-specific respiratory protection program, such a requirement would address in detail the selection, cleaning, storing, repair and replacement of respirators, as well as worksite-specific procedures when respirator use is required. EPA has decided not to expand the final rule to include the OSHA requirement to adopt a worksite-specific respiratory protection program because specific respirator requirements are described on EPA-approved, product-specific pesticide labeling. These product-specific respirator requirements are based on the acute inhalation toxicity of the end-use product or a comprehensive risk assessment informed by incident data, or on extensive pesticide active ingredient toxicology data, exposure science and epidemiology data (if available), or on both. Therefore, requiring a general worksite-specific respiratory protection program would duplicate the analysis underlying product-specific respirator requirements included on pesticide labeling. In addition, the WPS includes requirements for providing, inspecting, cleaning and maintaining PPE.

However, in consideration of the commenters who asked that EPA require compliance with all elements of OSHA requirements at 29 CFR 1910.134, the Agency re-evaluated other elements of that regulation. As part of that re-evaluation, EPA identified an inconsistency between the Agency's proposal and OSHA's requirements concerning a change schedule for the replacement of the gas- or vapor-removing canisters or cartridges. Specifically, OSHA requirements address change schedules that utilize NIOSH end-of-service-life indicator designations (29 CFR 1910.134(d)(3)(iii)(B)(2)). To ensure respirator protections are of greater consistency across industries, EPA has added the OSHA requirement that triggers the replacement of the gas- or vapor-removing canisters or cartridges to the list of conditions in the final rule at §170.507(d)(7) through an incorporation by reference.

<u>Comments - oppose.</u> Nearly all commenters expressed support for a general requirement related to proper respirator care and use, such as appears in the existing rule. However, many pesticide manufacturers and their associations, state farm bureaus and agricultural producer organizations questioned the feasibility of the proposed requirement for medical evaluations because locating qualified physicians practicing in rural areas would be difficult. Other farm bureaus and the SBA Office of Advocacy noted that the OSHA standard applies to general industries, shipyards, marine terminals, longshoring and construction, and it would not likely be easily adopted in agricultural settings.

EPA Response. EPA acknowledges that implementing respirator fit testing, training, and medical evaluation in agriculture will place additional burden on agricultural employers. However, the proper fit and use of respirators is essential in order to realize the protections respirators are intended to provide. EPA's pesticide risk assessment process relies on NIOSH protection factors (i.e., respirators used according to OSHA's standards) when deciding whether handler inhalation exposure can be mitigated by respirator use. If the handler inhalation exposure can be mitigated by a particular type of respirator, EPA may require the use of that respirator on the pesticide label, among other risk mitigation measures. Without the protection provided by the respirators identified on the label, use of those pesticides would cause unreasonable adverse effects on the pesticide user, i.e., the handler.

EPA is aware of several states, including California, Oregon and Washington, that have successfully incorporated all aspects of the OSHA standard for respirators in agriculture, demonstrating

the feasibility of applying OSHA's requirements in agriculture. North Carolina has incorporated many innovative ways to facilitate the medical evaluation and fit testing process, and helped farmers (including handler employers) locate reputable sources for online services for fit testing and medical evaluation, and sources for NIOSH-approved respirators, filters, and cartridges. EPA plans to work with stakeholders such as state regulatory agencies, universities, and others to provide outreach assistance such as training programs and written materials and to encourage the dissemination of information about fit testing and medical evaluation resources.

<u>Comments - access to medical evaluation for respirator users.</u> Many commenters, including growers and their associations, states and their associations, pesticide applicators and the pesticide industry, raised the issue of medical evaluation/clearance for respirator users, particularly for rural farmers.

<u>EPA Response.</u> EPA notes that many handler employers may be able to rely on online services where medical evaluations can be performed by relying on medical questionnaires. The employee would complete the medical questionnaire, which would be provided to the licensed medical professional for review. If the employee is cleared by the review, he or she is approved to wear a respirator. If the employee is not cleared through the review of the questionnaire, the employer may send the employee for further medical review or the employer may identify a different employee to handle the pesticide.

EPA acknowledges the new respirator requirements will be a change for handlers and handler employers, and EPA plans to work with stakeholders on outreach assistance addressing changes in respirator requirements and the impacts on pesticide labeling. Since WPS enforcement is primarily a state issue, various state agencies will have to be involved and communicate on appropriate training and enforcement issues.

<u>Comments - alternative medical clearance for respirator use.</u> Several organizations suggested that an alternative to the medical evaluation requirement would be for EPA or CDC-NIOSH to develop an agricultural respirator use medical screening questionnaire for potential respirator users, and then respirator users could voluntarily comply.

<u>EPA Response.</u> The final rule cross references and requires compliance with the OSHA standards for fit testing, training, and medical evaluation when a respirator is required by the labeling. By referencing existing work by OSHA, EPA is leveraging existing health infrastructure (the medical evaluation forms available for industry), which provides a consistent solution for general industry and agriculture. The medical evaluation is important for assuring that a respirator will prevent, rather than cause, adverse effects. OSHA has a medical evaluation questionnaire that is available on its web site, and EPA will include this information in compliance assistance materials.

Comments - use of respirators in agriculture versus industry. One farmer alliance drew a distinction between the use of respirators in a life threatening situations in industry versus the incidental use of respirators in agriculture, and proposed a chemical-specific pathway to respirator requirements based on acute toxicity. Similarly, one grower group and several state farm bureaus provided a perspective that the need for respirators is infrequent in agriculture and that mixer/loaders can take themselves out of harm's way easier than persons in an industrial environment regulated by OSHA requirements.

<u>EPA Response.</u> EPA notes that respirator requirements are established through the pesticide registration process, and the respirator requirements on pesticide labeling reflect the toxicity (acute, systemic, etc.) of its ingredients. When a respirator is required on pesticide labeling, EPA has conducted a scenario-specific assessment for the occupational handler based on the active ingredient, the pesticide formulation, and registered application rate. The final rule ensures that respirators used under the WPS

provide the same level of protection as comparable respirators used under OSHA's respiratory protection requirements.

<u>Comments - respiratory protection during tank cleaning.</u> One trade association identified several situations and recommendations regarding handler respiratory protection. Specifically, the comment noted that Immediately Dangerous to Life and Health (IDLH) precautions associated with OSHA's respirator regulations must be followed during pesticide tank or vessel cleaning.

<u>EPA Response.</u> Pesticide product labeling identifies required respiratory protection for handlers involved in mixing, loading, and applying a pesticide, or other activities associated with pesticide handling (e.g., cleaning up a spill or repairing contaminated equipment). EPA recognizes that there are other federal, state, or local regulations that may impact appropriate respirator use for confined space work.

<u>Comments - medical records.</u> One state department of agriculture expressed concern about the records for medical evaluation being covered by the confidentiality provisions of the Health Insurance Portability and Accountability Act (HIPAA), which would cause problems for state compliance officers.

<u>EPA Response.</u> To the extent that the results of a medical evaluation to determine fitness to use respirators would be considered medical records protected from disclosure under HIPAA, state inspectors may obtain access with the handler's authorization pursuant to 45 CFR 164.508, or without the need for authorization pursuant to 45 CFR 164.512, particularly §§ 164.512(d) and 164.512(f)(1)(ii)(C).

<u>Comments - definition of "licensed health care professional."</u> Several agricultural industry associations offered support for use and proper fit testing of respirators and requested a definition of "licensed health care professional."

<u>EPA Response.</u> The final rule requires "a medical evaluation by a physician or other licensed health care professional that conforms to the provisions of 29 CFR 1910.134 ..." OSHA's regulations at 29 CFR 1910.134(b) defines "Physician or other licensed health care professional" as an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by 29 CFR 1910.134(e).

<u>Comments - cost estimation.</u> Many commenters, including growers and their associations, states and their associations, pesticide applicators and the pesticide industry, commented on EPA's cost estimation relating to respirator fit testing, training, and medical evaluation for respirator users. Many of the comments pertained to concern over access to adequate medical evaluation for potential respirator users in rural areas of the U.S.

EPA Response. EPA has reviewed and revised its cost estimates for fit testing, training and medical evaluation. The cost estimate assumes that farms would designate one handler to be fit tested so the incremental costs for the filtering facepiece respirators reflects the need to fit test and train on multiple types of respirators. The increased costs also reflects the cost of the on-line medical evaluation, which replaces the estimated time of a medical technician reviewing the evaluation, and the cost of the employer's time to arrange (if off-site) or oversee (if on-farm) the evaluation and fit test, which was previously omitted. EPA has also updated wages, price of materials and services such as the cost of the medical evaluation and the fit test materials. Details of the revised estimate are available in the Economic Analysis for this final rule.

<u>Comments - respirator selection.</u> Many commenters, including growers and their associations, states and their associations, pesticide applicators and the pesticide industry, raised issues pertaining to

user safety and respirator selection, including 1) the types of respirators available for users, and 2) the need to address heat stress as part of the overall respirator requirement.

<u>EPA Response.</u> EPA recognizes that some handlers may not be able to use a tight-fitting respirator. Tight fitting respirators include filtering facepiece respirators, full and half face elastomeric respirators and tight fitting powered air purifying respirators (PAPR). EPA notes that the purpose of the medical evaluation is to ensure handlers are able to tolerate the physical burden caused by the use of respirators. Many medical conditions, such as cardiovascular diseases and the reduced pulmonary function caused by smoking, could impede the ability of the handler to wear a respirator without adverse health impacts. The medical evaluation should identify these potential issues and disqualify the handler from using a tight-fitting respirator. However, for these handlers, loose-fitting PAPRs are an option for respiratory protection because they do not require medical evaluations or fit testing.

EPA concurs that heat stress is an important element of worker protection and that heat stress, PPE and health and wellness should be included in training on respirator use in agricultural settings (i.e., outdoors). EPA anticipates that heat stress management will be included in its outreach assistance between issuance of the final rule and the compliance date.

<u>Comments - OSHA's jurisdiction in agriculture.</u> Some commenters, including a farm bureau, raised concerns that EPA's reference to OSHA's regulations could give OSHA legal grounds to pursue oversight of certain small farming operations, contrary to provisions of existing law.

<u>EPA Response.</u> EPA does not believe that including in the WPS a requirement that employers must perform respirator fit testing, training, and medical evaluation in accordance with OSHA's requirements by cross-reference to 29 CFR 1910.134 affects the scope of OSHA's jurisdiction. Today's final rule changes only the FIFRA WPS, which is implemented and enforced by EPA, states and tribes, and not by OSHA.

<u>Comments - respirator cartridge changeout.</u> One farmworker advocacy organization recommended that employers should be required to analyze work areas and processes in order to develop change schedules for filter cartridges to ensure filters are changed before their end of service life via one of the available tools available from OSHA and online advisors.

<u>EPA Response.</u> EPA acknowledges the utility in analyzing both work areas and/or similar job tasks to help evaluate potential risk concerns. In the final rule, there are several provisions that trigger replacement of filtering facepiece respirator and gas/vapor-removing canisters and cartridges. In addition to the provisions in the proposed rule, the final rule requires replacement when the maximum use time is reached, as determined by a change schedule conforming to the provisions of 29 CFR 1910.134(d)(3)(iii)(B)(2).

<u>Comments - respirator designation on pesticide labeling.</u> One PPE manufacturer recommended that EPA should take immediate action to update the pesticide labels to specify the current NIOSH-approved respirators under 42 CFR 84 because of confusion in EPA and stakeholder materials on occupational handler respirator requirements.

<u>EPA Response.</u> EPA is aware that some labels do not have the correct respirator designation. The correct language is in EPA's pesticide labeling guidance (the Label Review Manual) but has not been incorporated onto all pesticide labels. As part of the WPS roll-out, EPA plans to work internally and with stakeholders to raise awareness and understanding of the correct respirator designations in the Label Review Manual to facilitate the adoption of the correct respirator designations on labels.

<u>Comments - respirator filter selection information.</u> One PPE manufacturer identified a concern about appropriate selection information for N-, R- and P-series filters for filtering facepiece respirators;

specifically, that the selection criteria for the different series filters should be added to the regulatory text.

<u>EPA Response.</u> Respirator selection depends on the pesticide product being applied, and the user must comply with the respirator or replacement filter specifications in the pesticide product's labelling. It would be impractical to include in the WPS, or keep up to date, respirator selection information for each pesticide product.

<u>Comments – greenhouse respirator use.</u> One state farm bureau urged EPA to consult with respirator fitters and greenhouse plant growers in their expressed concern over 1) inadequate information for fit testing requirements for greenhouse workers and 2) the burdensome nature of meeting OSHA standards for respirators.

<u>EPA Response.</u> EPA acknowledges that implementing respirator fit testing, training, and medical evaluation in agriculture will place additional burden on agricultural employers. However, the proper fit and use of respirators is essential in order to realize the protections respirators are intended to provide. EPA recognizes the need to provide information on fit testing and medical evaluations to all sectors of the agricultural industry subject to the WPS including greenhouses. As part of the WPS roll-out, EPA plans to work with stakeholders to provide needed outreach assistance addressing changes in respirator requirements and the impacts on pesticide labeling.

B. Chemical-Resistant PPE

- 1. Current rule and proposal. The definition for "chemical resistant" in the existing WPS is a "material that allows no measurable movement of the pesticide being used through the material during use." Prior to the proposed rule, EPA received many comments from stakeholders suggesting that there was no way for agricultural employers, handlers, early-entry workers, pesticide educators and inspection personnel to ensure the PPE being used was "chemical resistant." EPA proposed requiring employers to provide PPE defined by its manufacturer as chemical resistant.
- 2. Final rule. EPA has rejected the proposed change. The final rule retains the existing definition of chemical resistance. The final regulatory text for this requirement is available at in 40 CFR 170.507(b)(1).
 - 3. Comments and responses.

Comments – definition of chemical resistant. Some commenters, including two state pesticide regulatory agencies, a university agricultural center, a farm bureau, a grower organization and a farmworker advocate, supported the idea of PPE manufacturers defining chemical resistant in principle, stating that this should clarify terminology and make it easier for agricultural employers to comply with PPE requirements. However, many commenters opposed EPA's proposed approach and questioned its feasibility. Specifically, some state pesticide regulatory agencies and their organizations questioned whether manufacturers can reliably designate PPE as chemical resistant in a permanent manner that would be easy for enforcement personnel to check during inspections. Many commenters of all types, including state pesticide regulatory agencies, grower organizations, farmworker advocates, pesticide manufacturers and PPE manufacturers raised concerns about assessing chemical resistance for the wide range of pesticide formulations and active ingredients. Some of the commenters stated that it is unreasonable to expect PPE manufacturers to test their PPE against all pesticide formulations and active ingredients. Other commenters suggested that the PPE manufacturers would have to identify the specific chemicals to which the PPE is resistant. Some commenters asserted that establishing a standard of chemical resistance is meaningless without defining permeation or test procedures. A few other commenters pointed out that there are test methods and standard test substances available that EPA could use. One PPE manufacturer asserted that the existing definition was purposefully worded to

ensure worker protection and that EPA's proposal over-simplifies a very complex and critical issue.

<u>EPA Response</u>. EPA recognizes the many comments highlighting the challenging issues involved with having PPE being defined as chemical resistant by the equipment manufacturer, who does not know the ingredients in every pesticide product. EPA agrees with commenters that the proposed approach would create more problems than it would resolve. Therefore, the final rule retains the existing chemical resistant definition.

Comments – other suggestions regarding chemical resistant or waterproof PPE. Some commenters, including grower organizations, a pesticide manufacturer organization and a university, urged EPA to reassess the situations where chemical resistant PPE is required by pesticide labels. In general, the commenters questioned whether certain PPE, such as footwear and hats, needs to be chemical resistant or if it is sufficient for the PPE to be waterproof. A few of these commenters pointed out that revising the requirement from requiring that PPE be chemical resistant to being waterproof goes beyond changing the WPS and would also involve revising the Label Review Manual and the pesticide labels that specify chemical resistant PPE.

<u>EPA Response</u>. EPA agrees that changing the label requirement for a certain piece of PPE from being chemical resistant to being waterproof involves more than updating the WPS regulation. EPA is currently reviewing the PPE statements in the Label Review Manual for accuracy and assessing whether pesticide labels include the most current and accurate PPE descriptions, based on other discussions with state regulatory agencies and other stakeholders. EPA will consider the comments on chemical resistance and waterproofness in the context of that effort. In addition, EPA realizes that its outreach associated with the WPS revision is a good opportunity to clarify confusion about what PPE is required, and therefore plans to develop guidance and outreach material on PPE where appropriate.

C. Contaminated PPE

- 1. Current rule and proposal. The existing WPS requires employers to ensure that PPE is cleaned before each day of reuse. If the article cannot be properly cleaned, the employer must dispose of it in accordance with applicable Federal, State, and local regulations. EPA proposed to add a requirement for employers to render unusable contaminated PPE that cannot be properly cleaned before it is disposed.
- 2. Final rule. In the final rule, the employer must ensure that contaminated PPE is made unusable as apparel or disposed of in such a way that it is unavailable for further use. EPA has also included in the final rule a requirement for the person who cleans, disposes, or otherwise handles the contaminated PPE to wear the gloves required for mixing and loading the pesticide that contaminated the PPE. The final regulatory text for this requirement is available at 40 CFR 170.507(d)(2).

3. Comments and responses.

Comments. Prior to the proposed rulemaking, state pesticide regulatory agencies expressed concern that unless proper measures are taken, contaminated PPE might be reused either as PPE or simply as a garment, placing the person wearing it at risk from pesticide exposure. Many organizations, including farmworker advocacy organizations, universities, public health organizations, a state department of public health, as well as individuals through two mass comment campaigns, expressed general support for the proposal to ensure that contaminated PPE be rendered unusable if it cannot be cleaned properly before it is disposed of. In support of the proposal, several commenters noted that rendering contaminated garments unusable would prevent adverse health effects. A state noted that the proposal was an effective method to reduce the potential for access to contaminated PPE. One grower organization noted that the potential for exposure exists when individuals cut or render contaminated PPE unusable, and suggested a requirement to seal the contaminated PPE in a disposal container and to dispose of the container in an appropriate manner.

In contrast, a state and some grower organizations stated that the current requirement is adequate and EPA should not adopt the proposal. Some farm bureaus opposed the proposal and thought the concern for individuals gaining access to contaminated PPE was well meaning yet hypothetical. Some of these commenters suggested it could lead to confusing violation scenarios, specifically from the interpretation of "render unusable."

Some states requested that EPA delete the provisions requiring contaminated PPE and contaminated glove liners to be disposed of in accordance with federal, state, or local regulations. They noted that if such regulations exist, the WPS does not add regulatory authority and adds another potential technical violation to the WPS. Further, they noted that states and localities can address disposal regulations as appropriate.

EPA Response. The final rule clarifies that the requirement is to make the PPE "unusable as apparel." EPA agrees that access to contaminated PPE might be prevented by sealing it in a container and entrusting it to a waste disposal system that effectively prevents diversion of waste, and that such an approach would reduce pesticide exposure to the person handling the contaminated article relative to many methods of rendering the PPE unusable. EPA has included in the final rule a provision allowing the PPE to be "made unavailable for further use" as an alternative to the proposed requirement to render the contaminated PPE unusable. To reduce the potential exposure to a person handling contaminated PPE, the final rule requires that a person must wear gloves while handling PPE covered by 40 CFR 170.507(d)(2).

EPA disagrees with comments from farm bureaus suggesting that there is little likelihood of persons accessing contaminated PPE. As mentioned in the preamble to the proposed rulemaking, state pesticide regulatory agencies have raised concerns for the potential reuse of contaminated PPE to EPA. EPA relies on state pesticide regulatory agencies to raise issues with implementation of the existing WPS that arise when they conduct inspections of WPS establishments. EPA has chosen to amend the existing rule in response to the input provided by the states.

EPA disagrees with states' request to delete provisions requiring contaminated PPE to be disposed of in accordance with federal, state, or local regulations. Although the WPS reference to federal, state, and local waste disposal regulations is somewhat duplicative, violations of those regulations can hardly be dismissed as "technical" violations, regardless of whether they are prosecuted under FIFRA or other authorities. However, the primary reasons for inclusion of these provisions in the WPS are to make clear that the WPS does not supersede federal, state, and local waste disposal regulations, and to remind employers of their responsibility to be aware of and comply with relevant disposal regulations.

XVI. Decision not to Require Monitoring of Handler Exposure to Cholinesterase-Inhibiting Pesticides A. Current rule and proposal.

The existing WPS does not have a requirement to monitor cholinesterase (ChE) levels in workers or handlers. In the proposal, EPA invited comment on whether to require routine ChE monitoring of handlers. However, because EPA's initial judgement was that the benefits of routine ChE monitoring would not justify the cost, EPA did not propose to add a requirement for routine monitoring of ChE inhibition in handlers.

B. Final rule.

The final rule does not include a requirement for routine ChE monitoring for handlers. *C. Comments and responses.*

Comments - general. In response to the proposal, several grower organizations, farm bureaus, crop consultants and their organizations, and states and their organizations expressed support for EPA's decision not to require a mandatory routine ChE monitoring program as part of the WPS. Several commenters stated that the most effective approach to prevent handler exposure to any pesticide product is to address the potential for exposure in advance of use, rather than after exposure has taken place. Many of these commenters agreed with EPA's assessment in the proposal that EPA's worker risk assessments and mitigation measures are sufficient to provide the necessary protection from pesticide exposure during handling. One commenter also suggested that requiring ChE monitoring may add to confusion and provide a false sense of safety to workers, health care providers, and regulators because it only measures exposure. These commenters suggested that the best approach that can be taken to mitigate exposure would be to address it through product-specific risk assessments supporting the registration of pesticide products, robust handler training on specific pesticides, and effective enforcement of label requirements.

In addition, some of the commenters objected that ChE monitoring is an invasive process, and that routine ChE monitoring would be extremely time-consuming and costly and would provide information of questionable value. One commenter stated that a proper ChE monitoring program would require that a baseline be established for employees, and that it would be highly unlikely that a baseline could be obtained for many workers because of previous exposure to organophosphate insecticides, while another commenter suggested that exposure to other common materials can change the levels of ChE, especially in serum level measurements, making it difficult to establish a baseline. Another commenter added that the timing of meals, stress, physical activity, and changes in body mass can cause ChE levels to fluctuate within an individual, and that the baseline value should be taken on the day of handling a ChE-inhibiting pesticide prior to exposure due to this intra-individual variability. The commenter suggested that baselines established every 1 to 2 years, as currently recommended by Washington State and California, respectively, would not provide meaningful information concerning the degree of exposure due to these daily fluctuations.

Conversely, several commenters, including some members of Congress, the California Department of Public Health, Washington State's Department of Health and Department of Labor and Industries, several public health organizations, academics, and farmworker advocacy organizations supported the idea of adopting a routine ChE monitoring program as part of this rulemaking, particularly for handlers who use ChE-inhibiting pesticides like organophosphates and N-methyl-carbamate pesticides. Many of these commenters cited the existing ChE monitoring programs in California and Washington State in their arguments for why ChE monitoring should be expanded nationally.

Some commenters stated that California and Washington have longstanding medical monitoring programs with proven track records in reducing exposure to, and illnesses from, highly neurotoxic chemicals. These commenters stated that the successful implementation of these monitoring programs has helped health professionals understand the effects of these classes of pesticides and prevent poisoning by identifying overexposure. Two commenters stated that Washington's program is effective and protects workers as reflected by worksite field evaluations of action level ChE depressions, which have identified multiple pesticide WPS violations that are believed to contribute to worker exposure. A couple of commenters stated that the benefits realized by the state programs, which would expand nationally if monitoring were to be required, include:

- Greater certainty about the frequency of pesticide overexposure.
- Avoidance of serious pesticide illness.

• Improved compliance with the WPS.

- Identification of any existing PPE, work practice, and engineering control requirements that are not sufficient to protect pesticide handlers from exposure.
 - Greater awareness of chemical and exposure hazards.

Some commenters cited Washington State's data that shows that the percentage of overexposed participating handlers who required remedial action fell from 20% when the program started in 2004 to 6% in 2013, for a reduction of 70%. These commenters stated that Washington's Department of Labor and Industries found that ChE monitoring helped identify the causes of overexposure, which allowed for those causes to be corrected by alerting employers and handlers to unsafe work practices, conditions, or equipment. Additionally, a couple of commenters stated that the percentages of handlers who actually reached the removal level from handling ChE-inhibiting pesticides remained consistently low after the implementation of the ChE monitoring program, with the percentages being 3.8% in 2004, 0% in 2010 and 2011, 2.3% in 2012, and 4% in 2013. These commenters believed that the sharp decline in the number of handlers needing remedial action, along with the consistently low percentage of handlers who exceeded 20% below their baseline (i.e., those who reach the evaluation level in the state programs), shows that the program has been effective in reducing exposure to OPs and carbamates, and that monitoring should be implemented nationally so that all workers receive similar benefits.

Some commenters in support of requiring ChE monitoring also discussed the costs associated with ChE monitoring. They stated that the cost of implementation should not deter EPA from requiring medical monitoring on a national level. A few commenters stated that EPA's estimate that the cost of ChE monitoring would average \$53 per year per agricultural establishment was a small cost when contrasted with the 70% reduction in overexposure according to Washington State's data. A couple of commenters also stated that monitoring in California and Washington has led to substantially fewer pesticide poisonings and reduced use of these highly toxic pesticides, and can, in turn, reduce long-term medical costs to farmworkers and the agricultural economy. Some commenters stated that EPA's analysis did not include an estimation of the medical expenses that were saved, the lost wages prevented, and the pesticide-related illnesses avoided as a result of early detection and intervention. As a result, the commenters believed that the benefits of a national ChE monitoring program would more than justify the costs given the severe effects of overexposure to ChE-inhibiting pesticides.

Other commenters supporting ChE monitoring stated that employees who handle ChE-inhibiting chemicals in non-agricultural sectors routinely receive the protection of medical monitoring. For example, some commenters stated that OSHA requires medical monitoring for workers who handle a wide range of toxic substances. They also stated that USDA requires monitoring of its employees who may be exposed to organophosphate or carbamate pesticides. These commenters stated that these safeguards should be provided for all workers who handle these pesticides, and therefore should be included in the final rule.

EPA Response. After reviewing the comments, EPA continues to believe that the expected benefits of a routine ChE monitoring program for handlers are not sufficient to justify the costs. As stated in the proposed rule, EPA believes that Washington State's efforts have identified the primary reasons for ChE inhibition among pesticide handlers. In many cases, ChE depression was caused by handlers not following basic safety and hygiene procedures, e.g., not wearing the label-required PPE and failing to wash before meals or bathroom breaks. Additionally, several handlers who did wear respirators as required by labeling had beards, which compromised the seal between the face and the respirator and reduced the protection intended to be afforded by the PPE. EPA believes that requiring expanded and more frequent handler training, in combination with requirements for fit testing and

training on proper respirator use for handlers, addresses the primary reasons for overexposure to ChE-inhibiting pesticides.

The revised labeling with increased protections and new mitigation measures resulting from the reregistration of organophosphates and carbamates will also result in lowered handler exposure. Reregistration has resulted in some uses of the most acutely toxic organophosphates being phased out. For the remaining uses, EPA has imposed additional PPE requirements, requirements for closed-system mixing and loading, and reductions to rates of application and number of annual applications permitted. As labels with updated PPE requirements for handlers are seen and followed in the field, EPA expects to see reduced numbers of overexposures. Additionally, the organophosphates and carbamates that are still registered are being used less frequently and being replaced by pesticides with lower risks, also reducing the potential for overexposure.

While EPA estimated the costs of a national, routine ChE monitoring program to be at least \$15.2 million annually, or about \$53 per agricultural establishment per year and \$120 per commercial pesticide handling establishment per year, this estimate does not include the full costs that would be expected of a national ChE monitoring program. As stated in the proposed rule, a national, routine ChE monitoring program would likely include program components such as training, recordkeeping, clinical testing, and field investigations, which were not included in the estimated costs because the initial \$15.2 million estimate appeared by itself to be disproportionately high in comparison to the expected benefits. Additionally, the estimated costs do not include the states' costs to build infrastructure to support ChE monitoring or to cover continued laboratory costs such as equipment maintenance and administrative support. If EPA were to calculate these additional costs, the estimated costs would be much higher than \$15.2 million annually. Therefore, EPA stands by its assessment in the proposed rule that the cost of implementing a national, routine ChE monitoring program is not justified by its limited benefits.

EPA believes that the increased handler protections being finalized in this rulemaking, combined with the product-specific risk mitigation measures, will appropriately address the elevated potential for ChE inhibition in handlers. Moreover, the training and PPE elements of the final rule will have the combined effect of providing important protective benefits to all pesticide handlers through increased knowledge of exposure risks and prevention strategies. This approach will lead to a reduction of pesticide exposures because it prevents handler exposure before it occurs.

Comments – monitoring handler exposure to cholinesterase inhibiting chemicals. Some commenters, including a state regulatory agency, a public health organization, and various farmworker advocate organizations disagreed with EPA's proposed decision to not implement medical monitoring for cholinesterase inhibiting pesticides, and noted that the concept of medical monitoring and the preventative measures that EPA is implementing in the final rule are not mutually exclusive. One health organization proposed the use of computerized Action Plans in conjunction with medical monitoring to preemptively address worker exposure concerns. One farmworker advocate organization commented that the only way to know whether the cumulative exposure to organophosphate pesticides has depressed cholinesterase levels to dangerous levels in either handlers or workers is through monitoring.

<u>EPA Response.</u> EPA acknowledges that monitoring employee exposures to organophosphate pesticides through cholinesterase monitoring has been successfully implemented in some states and may be a prudent occupational health practice in some occupational exposure situations. However, EPA stands by its assessment in the proposed rule that the cost of implementing a national, routine ChE monitoring program is not justified by its limited benefits. EPA believes that the increased handler protections being finalized in this rulemaking, combined with the product-specific risk mitigation

measures, will appropriately address the elevated potential for ChE inhibition in pesticide handlers. In addition to the training and new protections in the rule, EPA also makes a regulatory decision on each active ingredient and use site as part of the comprehensive occupational exposure and risk assessment under the FIFRA registration process in order to address worker safety concerns. The findings of the risk assessment are addressed in the registration decision for each pesticide product, and are manifested on the pesticide product labeling (e.g. application rate, use site). EPA believes that the registration decisions informed by the chemical-specific occupational risk assessment, in tandem with the training and PPE elements of the final rule, will protect handlers from unreasonable adverse effects of cholinesterase-inhibiting pesticides.

<u>Comments – national cholinesterase monitoring program.</u> One pesticide manufacturer organization commented on ChE monitoring programs noting that they not be used as a substitute for adherence to pesticide labelling and sound handler safety practices. This commenter also stated that the proposed enhancements of the WPS include aspects pertaining to training, communications, and PPE that are important protective benefits for all pesticide handlers through increased knowledge of exposure risks and prevention strategies, ultimately leading to reductions in potential exposure.

<u>EPA Response.</u> EPA agrees that compliance with the requirements on pesticide labeling and sound handler practices are important to limiting potential exposure to pesticides.

<u>Comments – cholinesterase inhibition.</u> One pesticide manufacturer organization commented on the difference in ChE inhibition between ChE-inhibiting pesticides like organophosphates and N-methyl-carbamate pesticides.

EPA Response. EPA thanks the commenter and agrees that there are toxicological differences between the nature of ChE-inhibiting chemical classes. EPA makes regulatory decisions based on the human health and ecological risk assessments for each active ingredient and cumulative chemical class, if appropriate. The toxicological databases for both individual active ingredients and the cumulative risk assessments for the organophosphate and N-methyl-carbamate chemical classes reflect differences based on the toxicological data submitted to EPA. EPA also agrees that when medical monitoring occurs, there may be logistical differences in the biological sampling to account for toxicological differences between chemical classes.

<u>Comments – overall protections.</u> One farmworker advocate commented that EPA doesn't sufficiently test or understand the chemical pesticides on the market and that there may be adverse effects for women and children as opposed to the protections provided by occupational exposure limits like OSHA's Permissible Exposure Limits (PELs) or NIOSH's Recommended Exposure Limits (RELs) established for given chemicals.

EPA Response. Although the scientific community's understanding of the biological and physiological effects of pesticides is always expanding, EPA believes that the range of studies currently required of applicants for pesticide registration provides an appropriate and reliable basis for determining whether a product meets FIFRA's registration standard of no unreasonable adverse effects on man or the environment. EPA conducts a rigorous human health risk assessment based on a given active ingredient's toxicological database, and exposure scenarios reflective of the site and method of each proposed use. For pesticide handlers, the exposure and risk assessment does not rely on occupational exposure limits (e.g. PELs or RELs), but rather a comprehensive scenario-driven assessment based on the use pattern identified on the product labeling to determine what use limitations, directions, and precautions would be necessary in order to prevent unreasonable adverse effects to handlers, other persons and the environment. Additional information on the assessment of pesticide

5056 handler risks is available on the Agency website: <a href="http://www.epa.gov/pesticides/science/handler-superinter-super-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-superinter-super-superinter-superinter-sup

XVII. Exemptions and Exceptions

A. Immediate Family

1. Current rule and proposal. The WPS currently exempts the owners of agricultural establishments from requirements to provide certain WPS protections to themselves and their immediate family members. Owners are required to comply with all applicable provisions of the WPS for any worker or handler employed on the establishment who is not a member of the owner's immediate family. The definition of "immediate family" in the existing rule includes only the owner's spouse, children, stepchildren, foster children, parents, stepparents, foster parents, brothers, and sisters. EPA proposed to expand the definition of "immediate family" to add father-in-law, mother-in-law, sons-in-law, daughters-in-law, grandparents, grandchildren, brothers-in-law, and sisters-in-law.

Note, too, that the WPS definitions of workers and handlers depend upon them being employed for compensation. Therefore, any person performing worker or handler tasks who does not receive a wage, salary or other compensation is not a worker or handler protected by the WPS, regardless of familial relationship to the owner.

EPA requested comment on but did not propose changes narrowing the immediate family exemption in two ways: (1) Limiting it only to those immediate family members of an owner of an agricultural establishment who are at least 16 years old, and (2) eliminating the exemptions from requirements regarding emergency assistance for workers and handlers and regarding handler monitoring during fumigant application.

As part of the proposal to establish a minimum age for pesticide handlers and early-entry workers, EPA proposed to add an exemption from the minimum age requirements to the immediate family exemption.

2. Final rule. EPA has finalized the definition of "immediate family" as limited to the owner's spouse, parents, stepparents, foster parents, father-in-law, mother-in-law, children, stepchildren, foster children, sons-in-law, daughters-in-law, grandparents, grandchildren, brothers, sisters, brothers-in-law, sisters-in-law, aunts, uncles, nieces, nephews, and first cousins. "First cousin" means the child of a parent's sibling, i.e., the child of an aunt or uncle. The final regulatory text for this definition is available at 40 CFR 170.305.

EPA has amended the exemption from certain provisions of the WPS for owners and members of their immediate families to include exemptions from the minimum age requirements for handlers and early-entry workers. The final regulatory text for this exemption is available at 40 CFR 170.601(a)(1)(i) and 170.601(a)(1)(xii).

EPA has clarified the final regulatory text related to the exemption from certain provisions of the WPS for owners and members of their immediate families. The exemption in the final rule will apply to owners and members of their immediate family on any agricultural establishment where a majority of the establishment is owned by one or more members of the same immediate family. The final regulatory text for this exemption is available at 40 CFR 170.601(a)(1).

EPA has not included in the final rule any of the other changes to the owner and immediate family exemption considered in the proposal.

3. Comments and responses.

<u>Comments</u>. Many commenters expressed general support for the proposed expansion to the definition of immediate family and the inclusion of an exemption from the minimum age requirement. Some commenters asserted that the definition provides greater clarity about who qualifies under the

immediate family exemption and will assist both the regulated community and state regulatory agencies in ensuring compliance with the proposed rule. One commenter noted that the proposed immediate family exemption may not affect California employers or workers because California's rules are more prohibitive. Another commenter contended that the immediate family exemption does not undermine the intent or protections of those the WPS is intended to protect but did not provide a specific rationale for this assertion.

Several commenters requested that EPA expand the definition to include cousins. Many commenters, including the SBA Office of Advocacy, requested that EPA expand the definition further to include aunts, uncles, nieces, nephews, and cousins. One commenter requested that EPA expand the definition to include nieces, nephews, and extended family. Commenters requesting further expansion of the definition noted that an expansion of the family members considered immediate family under the WPS would better reflect the reality of the family farm in America. Commenters also requested that EPA further expand the definition and exemption to recognize varying ownership patterns used to assure the continued operation of the farm and the involvement of siblings and their heirs. One commenter suggested that EPA align the exemption with USDA's interpretation of farm ownership by family members, which considers a "family farm" to be one where a majority of the farm is owned by family members, rather than retaining EPA's interpretation of the exemption as applying only on establishments that are wholly owned by one or more members of the same immediate family.

One commenter suggested that immediate family be determined by shared DNA, to be evaluated by the enforcement agency on a case-by-case basis. Another commenter urged EPA to include close-held corporate entities as family, if all workers are either parents or children of stock or share owners. A third commenter requested that EPA amend the definition and exception to require that the exemption would apply when the employee has an immediate family relationship with one of the owners. One commenter suggested deleting from the definition foster children.

A few commenters requested that EPA delete the definition of immediate family and eliminate the exemption. These commenters noted that risks from pesticide exposure are the same for family and non-family members, so all persons need the same level of protection regardless of their familial relationship to the owner. Other commenters requested that EPA eliminate the exemption for immediate family members under 16 or 18 years old to provide WPS protections to all children working with or around pesticides. One such commenter cited the number of injuries to working and non-working youth on farms in the U.S.

<u>EPA Response</u>. EPA has further expanded the definition of immediate family to also include aunts, uncles, nieces, nephews, and first cousins (i.e., child of a parent's sibling, child of an aunt or uncle) and is retaining the exemption in the WPS. EPA believes that the proposed definition of "immediate family" represents an appropriate accommodation to the social costs of the WPS to farm owners and members of their immediate families relative to FIFRA's requirement to prevent unreasonable adverse effects.

EPA considered commenters' requests to expand or contract the definition of "immediate family." Commenters suggested that a definition that includes cousins, or cousins, aunts, uncles, nieces and nephews would better reflect the actual patterns of family-based farm ownership in the United States. EPA agrees with commenters' suggestions that farm ownership may extend beyond relationships covered by EPA's existing or proposed definition. To accommodate the reality of family-based farm ownership patterns in the U.S., EPA agrees with commenters' requests to expand the definition to include aunts, uncles, nieces, nephews, and cousins. For clarity, EPA has chosen to include in the

definition "first cousins." A "first cousin" is defined as the child of a parent's sibling, i.e., the child of an aunt or uncle.

EPA has clarified the applicability of the exemption in the final rule in response to comments. The exemption in the final rule applies to the owners and their immediate family members on any agricultural establishment where a majority of the establishment is owned by one or more members of the same immediate family. A "majority of the establishment" means that more than 50 percent of the equity in the establishment is owned by one or more members of the same immediate family as defined in the WPS.

EPA agrees that the risks associated with pesticide exposure do not vary based on a person's relationship to the owner of the establishment. However, EPA recognizes that family-owned farms need flexibility and is relying on representations by family farm and small business advocates that those family members (including children) working on an establishment covered by the immediate family exception would be adequately prepared and supervised by family members. Although owners and their immediate family members are exempted from certain provisions of the WPS (e.g., providing pesticide safety training and specific decontamination supplies for immediate family members), they are obligated to follow the pesticide labeling and other WPS provisions that are established to protect workers and handlers from risks associated with specific pesticides. For these reasons, EPA has chosen not to eliminate the definition of immediate family or the exemption from certain portions of the rule for the establishment owner and members of his or her immediate family.

Although owners of establishments and members of their immediate family are exempt from some of the provisions of the rule, EPA expects that they will voluntarily follow the provisions from which they are exempt, or achieve equivalent risk mitigations through other means. EPA encourages owners and family members to carefully study the WPS requirements and assure themselves that they are not placing each other at risk of unreasonable adverse effects.

B. Crop Advisors and Employees

1. Current rule and proposal. The existing rule exempts employers from complying with certain handler requirements when the employee performs crop advising tasks in a treated area under an REI and is a certified or licensed crop advisor or directly supervised by a certified or licensed crop advisor. A certified or licensed crop advisor is one who has fulfilled the requirements of a program acknowledged as appropriate in writing by EPA or a state or tribal agency responsible for pesticide enforcement. The existing rule allows a certified or licensed crop advisor to make specific determinations regarding the appropriate PPE, decontamination and safe method of conduct for themselves and those working under their direct supervision. A person employed by a commercial pesticide handling establishment performing crop advising tasks after expiration of an REI is not subject to any provisions of the WPS. The rule also exempts employers from complying with worker requirements such as providing decontamination supplies and emergency assistance for certified or licensed crop advisors and for persons they directly supervise.

EPA proposed to eliminate the exemptions for employees directly supervised by certified or licensed crop advisors. EPA also proposed to eliminate the exemption from the worker decontamination and emergency assistance provisions for certified or licensed crop advisors employed as workers on agricultural establishments.

2. Final Rule. EPA has eliminated both exemptions as proposed. However, EPA has included in the final rule added flexibility in the PPE requirements for crop advisors and their employees. Specifically, EPA has added language to the final regulation that allows crop advisors and their employees who perform crop advising tasks while an REI is in effect to substitute the label-required

handler PPE with either the label-required PPE for early-entry activities or a standard set of crop advisor PPE. The standard set of PPE for crop advising tasks included in the final rule consists of coveralls, shoes plus socks, chemical-resistant gloves made of any waterproof material and eye protection if the labeling of the pesticide product applied requires protective eyewear for handlers. The final regulatory text for this requirement is available at 40 CFR 170.601(b) and 170.607(g).

3. Comments and responses.

Comments in support of eliminating the exemption. Comments from several state regulatory agencies, a farmworker advocacy organization and an independent crop consultant support EPA's proposal to eliminate the exemption currently in place for employees working under the direct supervision of a certified or licensed crop advisor. The state regulatory agencies and farmworker advocates stated that crop advisor employees should be provided protections consistent with other agricultural employees. An independent crop consultant discussed the changing nature of the business and noted:

"I don't even allow my own son to undertake certain tasks without some sort of accredited training. When something is going to unravel in this field, there is nothing a 'direct supervisor' can do to prevent something terrible from potentially happening. I've seen it happen too often. DO NOT PUT A WORKERS SAFETY IN THE HANDS OF A DIRECT SUPERVISOR."

<u>EPA Response</u>. EPA agrees that allowing workers to conduct crop advising tasks under direct supervision but without the same basic protections provided for other agricultural employees would establish a lesser standard of protection for similar types of work.

Comments in opposition to eliminating the exemption. Crop consultant associations, several state regulatory agencies, state farm bureaus, and one academic institutions objected to eliminating the exemption currently in place for employees working under the direct supervision of a certified or licensed crop advisor. They asserted that certified and licensed crop advisors often exceed the minimum safety training requirements when educating their employees and those employees are aware of the risks associated with their work. Some crop consultant associations noted that they are not aware of any case of endangerment or harm that has occurred to any employee under the direct supervision of a certified or licensed crop advisor.

The commenters also expressed concern that EPA underestimated the economic impact to crop advisors, and in turn to farmers, of eliminating this exemption, citing specifically the increased costs of additional PPE, the cost of work done by certified or licensed crop advisors instead of by their employees, and the cost of increased management time. The commenters contended that these increased costs could discourage investment in integrated pest management (IPM) and result in increased pesticide use that might put persons performing crop advising tasks at increased risk of pesticide exposure.

EPA Response. EPA has concluded that the burdens associated with eliminating the exemption for employees of crop advisors are justified by the additional protections provided to persons performing crop advising tasks who are not certified or licensed crop advisors. EPA has retained the exemption to the WPS for certified or licensed crop advisors because these individuals are highly trained about pesticide risks and how to protect themselves. EPA eliminated the exemption for crop advisors' employees because pest scouting tasks may result in substantial contact with a pesticide on treated surfaces in pesticide-treated areas. The amount of contact with pesticides during scouting depends on variables such as the height and density of the crop, the nature of the activity, the surface that contains the pesticide residue, and whether residues are dry or wet. While EPA recognizes that the crop advising industry has implemented a training program for employees, the program is not required and can vary

in content and quality from employer to employer. Additionally, crop scouts and assistant crop advisors are generally entry-level employees who may not feel empowered to ask an employer for PPE or other protections and may not understand the complex factors influencing risk well enough to take appropriate protective measures for themselves.

The existing incident monitoring programs do not capture illness data specifically associated with crop advising tasks because cases are categorized under a general "field worker" label. However, EPA's risk assessments indicate that people doing crop advising tasks during an REI are at risk of chronic, low-level pesticide exposure over time. PPE requirements and availability of decontamination supplies during and after an REI are fundamental to mitigating risks of concern for persons performing crop advising tasks.

EPA understands that IPM programs require post-application entry and the timing is critical to efficacy. By retaining the exemption for certified or licensed crop advisors to conduct crop advising tasks during an REI and allowing flexibility for employers to substitute the label required PPE for handlers with either PPE for early-entry workers or a standard set of PPE, the increased costs noted in comments are reduced. Eliminating the exemption for a non-certified crop advisor to forgo wearing PPE based on his/her employer's recommendation seems misunderstood by those commenting on the perceived impact. The WPS currently requires employers of non-certified crop advisors to make PPE available. The final regulation requires that employees working under a certified crop advisor in a field during an REI use a standard set of PPE (consisting of coveralls, shoes plus socks and chemical-resistant gloves, and eye protection if the pesticide product labeling applied requires protective eyewear for handlers) or label-required PPE. That is, the impact of the provision is that the non-certified crop advisor may have to put on a pair of coveralls, gloves, and in some instances, eye protection. The benefit of this revision is to remove a potential externality and protect employees who may not be fully trained and may be unable to make appropriate judgments regarding personal risk.

C. Closed Systems

- 1. Current rule and proposal. The existing WPS permits exceptions to the label-specified PPE when using a closed system for certain pesticide handling activities. The existing rule does not adequately describe the specific characteristics of an acceptable closed system. EPA proposed to establish specific design criteria and operating standards for closed systems based on California's existing standards outlined in the California Department of Pesticide Regulation's (CDPR) 1998 Closed Systems Director's Memo (http://www.cdpr.ca.gov/docs/whs/cac/cacwhs98-01.pdf).
- 2. Final Rule. EPA has modified the proposed approach regarding closed systems. Specifically, in the final rule EPA has adopted a broad definition, a performance-based standard, and basic operating standards. The operating standards require the handler employer to ensure that written operating instructions for the closed system are available, that the handler receives training on use of the closed system, and that the system is maintained according to the written instructions. Specific design criteria and recordkeeping requirements that EPA proposed are not included in the final rule.

The final rule retains the existing requirements for PPE when a closed system is used: Labeling-mandated PPE must be immediately available for use in an emergency and handlers must use protective eyewear for closed systems that operate under pressure.

The final regulatory text for the definition of closed systems is available at 40 CFR 170.305. The final regulatory text for the closed system exception is available at 40 CFR 170.607(d)(3).

3. Comments and responses.

<u>Comments</u>. Most comments that addressed closed systems supported the goal of encouraging their use as an engineering control through a WPS exception; however, very few individuals, states or

organizations supported the proposal as written. Several farmworker advocacy organizations, public health organizations, universities, and private citizens suggested that EPA require closed systems for all Toxicity Category I pesticide products rather than continuing the voluntary system.

Comments from states and grower and industry associations supported the existing voluntary, performance-based system and objected to the proposed specific design criteria, noting a number of weaknesses in the criteria. Specifically, they noted that the pressure requirements were too prescriptive and would not allow effective mixing, that the proposal did not address water soluble packaging or lock and load systems used for dry formulations, and that the complicated requirements would be a deterrent to increased adoption of closed systems. A number of commenters also noted that the design standards are too restrictive to accommodate future innovation. States commented that assessing compliance with the design standard would require extensive inspector training and could result in technical violations without providing additional handler protection. Many commenters from the pesticide industry and grower associations also stated that EPA underestimated the costs of closed systems in the proposed rule partly because existing closed systems would need to be upgraded to meet the proposed standards. A number of commenters felt that EPA depended too heavily on CDPR's evaluation of closed systems.

<u>EPA Response</u>. EPA considered the comments submitted and was convinced that the prescriptive requirements in the proposal would be a disincentive to the voluntary adoption of closed systems. In response, EPA has finalized a closed system performance standard that will permit flexibility for the system while meeting the protection goals.

In response to comments advocating that EPA require closed systems for all Toxicity Category I pesticides under the rulemaking, EPA reminds the commenters that worker risk assessments and the risk management processes establish the required protections that appear on product labels. EPA identifies the basic protections, often PPE, to protect handlers from risks of concern. If handler exposure during mixing and loading is above the established level of concern, and if PPE does not reduce exposure to below the level of concern, the pesticide label may require a closed system for mixing and loading. EPA has required the use of closed systems on some product labeling.

EPA recognizes that the reduction in handler PPE alone is not likely to be enough incentive for an employer to use closed systems. However, EPA is convinced that on larger establishments, the efficiency and comparative protection value of a closed system, combined with the reduction in PPE that must be worn by the handler, may induce users to adopt closed systems. Establishing requirements for such closed systems – whether required or used voluntarily – is necessary to protect handlers, who could be exposed to concentrated pesticides if they use poorly designed or constructed closed systems.

EPA agrees with the comments that a broad definition of "closed system" will encourage industry innovation better than the proposed prescriptive rule and will allow flexibility for employers to design systems specific to their needs. A broad performance standard, along with requirements concerning operating instructions, training and maintenance, will enable employers, handlers and regulatory personnel to determine whether a closed system qualifies for the exemption. The operating standards will ensure that the closed systems are used as intended and are adequately maintained.

EPA considered CDPR's proposed rule in the development of the final closed systems standard because they are a nationally recognized expert in closed-system regulation. California is the only state with specific closed system standards, and has required their use with certain chemicals since the 1970s. EPA notes that CDPR no longer supports use of the prescriptive-based criteria upon which EPA modeled the proposal outlined in the NRPM. In December 2014, CDPR published proposed regulations outlining a simplified, performance-based criteria for closed system design. CDPR developed their revised closed

systems standard and discussed the proposal with representatives from groups that will be directly affected including agricultural producer organizations, manufacturers, applicators, and growers, as well as at CDPR's Pesticide Registration and Evaluation Committee and the Agricultural Pest Control Advisory Committee and Pest Management Advisory Committee meetings. EPA's final closed system requirements were developed using CDPR's proposal as a model and do not conflict with CDPR's proposed closed system requirements.

Section 170.607(d)(2)(i) establishes a performance standard for closed systems. Specifically, a closed system must remove the pesticide from its original container and transfer the pesticide product through connecting hoses, pipes and couplings that are sufficiently tight to prevent exposure of handlers to the pesticide product, except for the negligible escape associated with normal operation of the system. This closed system performance standard is based on the criteria for closed systems in section 6746(f)(1) of CDPR's proposed regulations with a few changes, partly to accommodate the different terminology in the two sets of regulations. Also, EPA adjusted the requirement to apply to transferring any pesticide product rather than a pesticide concentrate so the WPS criteria would apply to transferring liquid formulations and dry formulations whereas California's proposed requirements would only apply to liquid formulations. Lastly, EPA added the phrase "except for the negligible escape associated with normal operation of the system" to provide the flexibility intended in the proposed rule. The existing WPS describes a closed system as preventing the pesticide from contacting handlers or other persons, which is a very high standard because it does not allow any exposure. The phrase "except for the negligible escape associated with normal operation of the system" is intended to account for the expected or predictable small release of pesticides from existing closed systems when hoses, pipes and couplings are disconnected. EPA recognizes that there will often be a small amount of material in the hoses, pipes and couplings to which the handler possibly could be exposed. EPA has not quantified the maximum amount of pesticide escape that is acceptable, but notes that it should be consistent with the intent of a closed system, which is to prevent contact to the handlers or other persons.

EPA also adjusted the final regulatory text for closed systems to address the comments about water soluble packaging. The regulatory text in the final rule was revised to state clearly that the closed system exception from PPE applies when intact, sealed water soluble packaging is loaded into a mixing tank or system. The regulation also clarifies that water soluble packaging is no longer a closed system if the integrity of the packaging is compromised. This language in the final rule incorporates EPA's current position about water soluble packaging and closed systems, as established in the Interpretive Guidance on the WPS (http://www.epa.gov/pesticides/safety/workers/wpsinterpolicy.htm).

While the final rule includes only a performance standard, EPA recognizes that it may be helpful to have guidance on how to construct a system to meet that standard. As part of California's proposed rulemaking, CDPR and the University of California, Davis (UC Davis) developed plans for building a closed system to release along with the proposal. The "Overview of Closed Systems Components and User Designs" document includes lists of component parts (and costs) for three levels of systems (basic, medium and high). The design plans developed by CDPR and UC Davis will provide users with examples of representative closed systems components so they can identify or develop acceptable closed systems.

The changes to replace the proposed specific design standards with a broad performance standard in the final rule address commenters' concerns with cost estimates in the proposal, because employers will be able to continue using most existing closed systems with minimal adjustments. In addition, EPA notes that the WPS does not require use of closed systems, so commenters who assumed

many pesticide users would have to purchase expensive closed systems were incorrect. EPA adjusted the closed system cost estimates from the proposed rule in several ways to reflect changes in the final rule. The cost estimate in the proposed rule assumed that some users of closed systems would purchase new systems while others would revert to using PPE. In light of the revised definition, the final cost estimate assumes that most users would simply purchase an adapter to connect their existing closed system to the pesticide container, which is the part that most likely needs to be added to convert existing mechanical transfer systems to be closed systems that meet EPA's criteria. These changes and costs are based on the CDPR and UC Davis document "Overview of Closed Systems Components and User Designs," which includes lists of component parts and their costs for three levels of systems. In addition, the cost of developing operating instructions was added, assuming that most closed systems are custom-made systems that would require the employer to develop operating instructions, while the costs of keeping records of maintenance was deleted. EPA reduced the estimated number of farms using closed systems based on information from the Agricultural Handler Exposure Task Force, which showed that the limited number of pesticide users who use closed systems are primarily larger establishments and commercial pesticide handling establishments. Therefore, the estimated costs of the closed system criteria decreased from the proposed rule to the final rule.

Using closed systems is preferred to wearing PPE as an approach for managing chemical exposure in the "hierarchy of controls" established under standard industrial hygiene principles. Enclosing the chemical and substantially reducing the potential for exposure at the source reduces the potential for subsequent exposure to handlers, other people, and the environment.

EPA estimates the cost of the final closed system requirements will be \$2.1 million annually. EPA estimates that cost per agricultural establishment will range from \$5-\$30 per year, and the cost per commercial pesticide handling establishment will be about \$21 per year. EPA estimates that on family establishments, the cost would range from \$1-\$30 per year. Many commenters from the pesticide industry and grower associations stated that EPA underestimated the costs of closed systems in the proposed rule partly because existing closed systems would need to be upgraded to meet the proposed standards. The changes to replace the proposed specific design standards with a broad performance standard in the final rule address these comments, because employers will be able to continue using most existing closed systems with minimal adjustments. For details refer to the Economic Analysis accompanying this rule (Ref. 1). In addition, EPA notes that the WPS does not require use of closed systems, so commenters who assumed many pesticide users would have to purchase expensive closed systems were incorrect.

EPA adjusted the closed system cost estimates from the proposed rule in several ways to reflect changes in the final rule. The cost estimate in the proposed rule assumed that some users of closed systems would purchase new systems while others would revert to using PPE. In light of the revised definition, the final cost estimate assumes that most users would simply purchase an adapter to connect their existing closed system to the pesticide container, which is the part that most likely needs to be added to convert existing mechanical transfer systems to be closed systems that meet EPA's criteria. These changes and costs are based on the CDPR and UC Davis document "Overview of Closed Systems Components and User Designs," which includes lists of component parts and their costs for three levels of systems. In addition, the cost of developing operating instructions was added, assuming that most closed systems are custom-made systems that would require the employer to develop operating instructions, while the costs of keeping records of maintenance was deleted. EPA reduced the estimated number of farms using closed systems based on information from the Agricultural Handler Exposure Task Force, which showed that the limited number of pesticide users who use closed systems are

primarily larger establishments and commercial pesticide handling establishments. Therefore, the estimated costs of the closed system criteria decreased from the proposed rule to the final rule. D. Aerial Applications - Eyewear Protection for Open Cockpits

- 1. Current rule and proposal. Under the existing WPS, where labeling requires eye protection, the requirement may be satisfied by goggles, face shield, safety glasses with front, brow and temple protection, or a full face respirator. The existing WPS allows aerial applicators applying pesticides from open cockpit aircraft to substitute a visor for label-required eye protection. Because the term "visor" can be used to refer to the brim of a cap that provides only shade and offers little eye protection from pesticide sprays, EPA proposed to clarify the requirement by removing the term. EPA proposed to allow aerial applicators to substitute a helmet with the face shield lowered for the label-required eyewear, because this more clearly indicates EPA's expectation of a clear visor that covers and adequately protects the eyes.
- 2. Final rule. In the final rule, EPA has removed the term "visor." The final rule allows the substitution of a helmet with face shield lowered for labeled protective eyewear for aerial applicators in aircraft with open cockpits. The final regulatory text for this requirement is available at 40 CFR 170.607(f)(2).
 - 3. Comments and responses.

<u>Comments.</u> There were very few comments addressing this proposal. One state suggested EPA consult with relevant aerial agencies responsible for overseeing the use of open cockpits for making pesticide applications to see if the proposal is feasible. One state regulatory agency supported the proposed changes along with a state academic institution and a farmworker advocacy organization. Two farm bureau organizations said they had no objection the proposal, while another farm bureau organization and a commodity group said they deferred to or supported comments from aerial applicator associations.

An aerial applicators association asserted that aerial applications of pesticides using open cockpit aircraft are very rare and that EPA is solving a problem that does not exist. They objected to handlers operating open cockpit aircraft being required to wear the same PPE as handlers operating open cab ground equipment. They did not highlight any specific issue with the helmet and visor being lowered when protective eyewear are required, but generally objected to EPA proposing any rule that in any way impacted aviation safety and recommended deleting this and other provisions applicable to aerial applicators.

EPA Response. EPA acknowledges that while open cockpit aircraft may be rare, available exposure data indicate that even pilots in enclosed cab aircraft are exposed to the pesticides they apply. Ensuring that the eye is protected from pesticides is required by the product labeling. Helmets with face shields in the lowered position provide acceptable eye protection, but many items referred to as "visors" offer no eye protection from pesticide sprays. EPA believes it is common for some aircraft pilots to wear helmets with face shields, so this practice should not present a hazard or safety issue for pilots. Additionally, EPA is unaware of any adverse problems that have arisen because of the existing WPS requirements related to aerial applicators and PPE; therefore EPA is retaining this provision as proposed and the other related provisions for aerial applicators and PPE as they were in the existing rule. *E. Aerial Applications – Use of Gloves*

1. Current rule and proposal. In the existing rule, aerial applicators have the option of whether to wear chemical resistant gloves to enter and exit the aircraft unless gloves are required by the product labeling. In the proposal, EPA inadvertently inserted the regulatory language that existed prior to the 2004 rule revision that required pilots to wear chemical resistant gloves.

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2. Final rule. The final rule retains the exception in the existing WPS that offers aerial applicators the option of wearing chemical-resistant gloves when entering and exiting the aircraft, except when the product labeling requires that chemical-resistant gloves be worn when entering and exiting the aircraft. The final regulatory text for this requirement is available at 40 CFR 170.607(f)(1).

3. Comments and responses.

Comments. Several commenters, including aerial applicators, aerial applicator associations and agricultural industry noted this inadvertent error in the proposal and noted that they had learned it was an oversight, but they reiterated support for keeping the requirements the same as they are in the existing rule. The commenters also asserted the use of gloves presents a hazard to pilots who may fall when entering and exiting the aircraft when wearing gloves. They also suggested contamination from contact with the exterior of the aircraft is minimized due to advances in application techniques (e.g., GPS) that help pilots avoid flying through their spray.

EPA Response. EPA agreed with commenters that said to keep the existing requirements for gloves in cockpits without changes. The final rule retains the exception in the existing regulation that offers aerial applicators the option of wearing chemical-resistant gloves when entering and exiting the aircraft, except when the product labeling requires that chemical resistant gloves be worn entering and exiting the aircraft.

F. Enclosed Cabs – Changes to Exceptions to PPE Requirements when Applying Pesticides from Inside an **Enclosed Cab**

1. Current rule and proposal. The existing WPS permits exceptions to the labeling-specified PPE when handling tasks are performed from inside an enclosed cab that meets the specifications defined in the rule. These exceptions are based on the dermal protection provided by the enclosed cab, which prevents pesticides from contacting the body, and allow handlers to substitute a long-sleeved shirt, long pants, shoes, and socks for the labeling-specified PPE. The existing rule requires persons occupying an enclosed cab to use labeling-required respiratory protection, except where the cab has been certified by the manufacturer to provide respiratory protection equivalent to the handler respiratory protection required by the pesticide labeling.

EPA proposed to exempt handlers from all labeling-specified respiratory protection PPE requirements when applying pesticides from inside an enclosed cab. This would have allowed handlers to substitute a long-sleeved shirt, long pants, shoes, and socks for the labeling-specified PPE in all cases no matter what type of respiratory protection PPE was required by the labeling.

2. Final rule. In the final rule, EPA requires handlers in enclosed cabs to wear the labelingspecified respiratory protection except when the only labeling-specified respiratory protection is a filtering facepiece respirator (NIOSH approval number prefix TC-84A) or dust/mist filtering respirator. In the final rule, handlers in enclosed cabs may substitute a long-sleeved shirt, long pants, shoes and socks for the labeling-specified PPE for skin and eye protection. If a filtering facepiece respirator (NIOSH approval number prefix TC-84A) or dust/mist filtering respirator is required by the pesticide product labeling for applicators, then handlers do not need to wear the respirator inside the enclosed cab provided that the enclosed cab has a properly functioning air ventilation system that is used and maintained in accordance with the manufacturer's written operating instructions. If any other type of respirator is required by the pesticide labeling for applicators, then the handler must wear the respirator inside the enclosed cab during handling activities.

EPA has retained the other conditions of the existing WPS exception to PPE requirements for handlers using enclosed cabs. Specifically, all of the PPE required by the pesticide product labeling for applicators must be immediately available to handlers in an enclosed cab and be stored in a sealed

container to prevent contamination. Handlers must wear the applicator PPE if they exit the cab within a treated area during application or when a REI is in effect. Once PPE has been worn in a treated area, handlers must remove it before reentering the cab to prevent contamination of the cab.

The final regulatory text for the enclosed cab exception is available at 40 CFR 170.607(e).

3. Comments and responses.

<u>Comments</u>. EPA did not receive any comments in opposition to the proposed changes to the enclosed cab exception. One grower noted that the enclosed cab exception is an excellent component of the proposal. Another commenter noted that respirator use is infrequent since the spraying operation takes place from inside an enclosed, climate-controlled tractor cab.

EPA Response. EPA considered the comments submitted but has retained the existing exceptions with minor changes. Although EPA considered a more expansive exception under its proposal, after reevaluation of the potential exposure risks for handlers and the protections afforded by enclosed cabs, EPA determined that enclosed cabs may not universally provide respiratory protection necessary to mitigate inhalation risks for any pesticide product that required respiratory protection greater than a filtering facepiece respirator (NIOSH approval number prefix TC-84A) or dust/mist filtering respirator. EPA determined that enclosed cabs may not provide adequate protection from inhalation exposure hazards when the inhalation exposure risk arises from vapors or other non-particulate inhalation hazards. Additionally, EPA has learned that there are no longer any enclosed cab manufacturers certifying cabs to provide respiratory protection and the American Society of Agricultural and Biological Engineers has withdrawn their enclosed cab standard. Based on this information, EPA has removed provisions under the enclosed cab exception that permit persons occupying an enclosed cab to eliminate certain labeling-required respiratory protection PPE if the cab has been certified by the manufacturer to provide respiratory protection equivalent to the respiratory protection required by the pesticide labeling.

XVIII. General Revisions

A. Label vs. Labeling

1. Current rule and proposal. FIFRA defines the label as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." 7 U.S.C. 136(p)(1) For reasons of space and user convenience, detailed use instructions and precautions often appear in labeling provided with the pesticide product upon sale. As defined in FIFRA, "labeling" includes "all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time; or to which reference is made on the label or in literature accompanying the pesticide or device..." 7 U.S.C. 136(p)(2).

Labeling may include booklets distributed with the product when such documentation is too long to be included on the label that is securely attached to the container. For example, some products have labeling that is 60 or more pages long. FIFRA and EPA regulations require certain information to appear on the label – on or attached to the pesticide container. Other information necessary to use the product safely, such as directions for use, may be included in a booklet distributed with, but not securely attached to, the container (40 CFR 156.10(i)(1)(ii)); this information could also be available on the Internet if the producer has decided to provide web-distributed labeling for the product (Ref. 21). In either format, the information would be considered labeling. Labeling sometimes includes enforceable references to other documents that do not physically accompany the container, such as the WPS.

The existing rule discusses employers' responsibilities related to pesticide labels and labeling in several places. The existing rule requires agricultural and handler employers to ensure that pesticides are used in a manner consistent with the labeling. When the emergency assistance provisions of the

WPS are triggered, the existing rule requires employers to provide information from the product labeling to affected workers, handlers, and/or treating medical personnel. Handlers must receive training on the format and meaning of information contained on pesticide labels and in labeling. Finally, employers must ensure that handlers have either read or have been informed in a manner they understand of all labeling requirements related to safe use of the pesticide, and that the handler has access to the product labeling during handling activities.

Although the proposal reorganized the rule, some of the requirements for the existing rule outlined in the previous paragraph remained essentially unchanged in the proposed rule, e.g., agricultural and handler employers' responsibility to ensure that pesticides are used in a manner consistent with the labeling. The proposal included a requirement for employers to maintain copies of the pesticide labeling for each pesticide used on the establishment for 2 years from the date of application. The proposal also would have required the employer to provide a copy of the label and the product's SDS when the emergency assistance provisions are triggered, rather than to provide information from the pesticide labeling.

2. Final rule. Where the proposed rule would have required the employer to provide a copy of the pesticide label, or specific information from the labeling, and the SDS under the emergency assistance provisions, the final rule only requires the employer to provide the SDS and specific information, which can be obtained from the pesticide application and hazard information display, rather than the label or labeling. See Unit XIV. for other comments, EPA's responses and the final regulatory text related to emergency assistance. The final rule eliminates the proposed requirement for employers to maintain copies of the labeling, rather than the label, for each product bearing a WPS requirement on the labeling, and replaces it with a requirement for the employer to retain specific information about the product used and the application, as well as the SDS. See Unit VII. for other comments, EPA's responses and the final regulatory text related to this requirement.

For handler training requirements, EPA has amended the language in the final rule to delete the word "all" related to labeling. The final rule requires handlers to receive training on following the portions of the labeling applicable to the safe use of the pesticide and on the format and meaning of information contained on pesticide labels and in labeling applicable to the safe use of the pesticide. The final regulatory text for these provisions is available at 40 CFR 170.501(c)(3)(iii)-(iv).

For labeling and application-specific information the employer must provide to the handler, EPA has amended the final rule to require the employer to provide the handler with information on all portions of the labeling applicable to the safe use of the pesticide, rather than on all labeling requirements. The final regulatory text for this provision is available at 40 CFR 170.503(a).

3. Comments and responses.

<u>Comments</u>. Commenters raised issues with EPA's use of the term "labeling" in the proposed rule. Commenters raised specific concerns with the use of the broader "labeling" in various requirements instead of limiting those requirements to just the label. These concerns arose in regard to agricultural and commercial pesticide handler employer duties, emergency assistance, hazard communication, and handler training and establishment-specific information.

Some commenters generally disagreed with EPA's use of "labeling" and requested that EPA use "label" instead throughout the rule. They asserted that labeling is too broad and that labeling includes materials not attached to the container, such as advertisements, brochures and pamphlets.

Commenters assert that the broadness of "labeling" applied to requirements to provide or retain this information could result in a requirement on employers to track down many ancillary pieces of

information for a complete record, or to face a technical violation for failure to retain all elements of the labeling.

Under the agricultural and commercial pesticide handler employer duties, at 40 CFR 170.9(a) and 170.13(a) of the proposal, commenters said that EPA's use of labeling was too broad. They asserted that employers' liability should be only to comply with the WPS rather than with the label or all relevant labeling because making the employer responsible for complying with all labeling exceeds the scope and intent of the WPS. They also noted that certified applicators, those competent to use pesticides according to the labeling instructions and who make the actual applications, should be required to comply with the labeling, but that the agricultural employer should not.

In regard to emergency assistance, commenters requested that EPA delete the reference to labeling and replace it with a requirement to provide the label and EPA registration number of the product. Commenters note that this requirement would be sufficient to provide appropriate information for emergencies.

Commenters also requested that in the section on pesticide application and hazard information, EPA delete the requirement for the employer to maintain copies of the labeling for all WPS-labeled pesticides used on the establishment, and instead to require the employer to maintain a copy of the label and EPA-registration number. Again, commenters noted that such a requirement would likely result in technical violations without providing benefit to workers or handlers.

In the sections on handler training and establishment-specific information, commenters took issue with requirements to train handlers on all labeling and to ensure that for specific applications handlers have read the labeling or have been informed of all labeling requirements. Commenters noted that a requirement for handlers to be trained on all labeling requirements, rather than those pertinent to their specific tasks, would be overly broad and unnecessary. Commenters requested that EPA replace "labeling" with "label" in these sections. A commenter also requested that EPA distinguish between types of handlers and limit the requirement to provide access to labeling to handlers at mixing and loading sites, rather than impose the same requirement in regard to all handlers, including those making applications.

<u>EPA Response</u>. EPA disagrees with commenters' request to replace "labeling" with "label" throughout the regulation because the broader term is appropriate in many provisions of the WPS. The FIFRA scheme for managing the risks of pesticide products rests primarily on mandatory use directions and precautionary statements approved by EPA in the registration process and communicated to users through labels and labeling. Although in the case of lower risk products intended for general consumer use, this information typically fits on the label, this is not the case for many agricultural and commercial-use pesticides.

Labeling does not include advertisements, pamphlets or brochures unless they accompany the product when sold or are referenced on the labeling. For instance, EPA has indicated that documents such as marketing brochures used to sell the product and to provide information to customers and is not labeling as defined by FIFRA section 2(p).

(http://www.epa.gov/pesticides/regulating/labels/labels_faq/lr_faq_10.html) If a document of this type does not accompany the product when sold and there is no reference to the bulletin on the product label, it is not "labeling." Note though, that non-labeling documentation related to a product must not have claims that differ from the product label. 7 U.S.C. 136j(a)(1)(B).

Because mandatory use directions often appear in the labeling of agricultural pesticides, rather than the label, some provisions of the WPS appropriately use the word "labeling." Where the word "labeling" appears in the WPS, employers are responsible for following or providing labeling as defined

in FIFRA. This does not require employers to find, retain, or provide advertisements, pamphlets or marketing brochures that do not meet the definition of "labeling."

For example, it is appropriate that agricultural and handler employers' duties under the final rule include ensuring compliance with "labeling" rather than just the label. The existing regulation has the same requirement under general duties and prohibited actions. 40 CFR 170.7(a)(2). The labeling may include directions for use or other information essential to the safe and effective application of the pesticide, or specific information related to WPS protections, such as the REI. For these reasons, EPA has decided not to replace "labeling" with "label" throughout the final rule as suggested by the commenters.

Furthermore, the obligation of certified applicators (or any other person applying a pesticide) to follow the labeling does not negate the obligation of agricultural and handler employers to comply with the labeling. Requirements related to the WPS are found both in the regulation (e.g., training, application-specific information) and on specific product labeling (e.g., directions for use, REI, PPE). In addition, other non-WPS elements of the labeling, such as application rates and maximum number of applications to a crop, are relevant to protecting workers and handlers from occupational exposure to pesticides. When employers choose to use a pesticide that references the WPS on the labeling on their establishment (either as the applicator or by directing another person to apply the pesticide on their behalf), they are obligated to ensure that all requirements of the labeling are followed, not only those related to the WPS, to ensure that workers and handlers are adequately protected.

However, EPA agrees that certain WPS requirements could be limited to the information on the label or specific information from the label, and has specified "label" instead of "labeling" or specific information from the label where appropriate. For example, EPA agrees with commenters that employers need not provide all labeling in the event of the emergency. In the current rule, EPA lists specific information that must be provided to a potentially injured worker or handler, or to treating medical personnel: Product name, EPA registration number, active ingredients, antidote, and first aid and medical treatment information. Since all of this information is required on the label (40 CFR 156.10(a)(1)), the final rule allows the employer to provide a copy of the label or this specific information from the label, in addition to providing a copy of the SDS, when emergency assistance is required.

EPA also agrees with commenters' request to eliminate the requirement for employers to maintain copies of the labeling for all pesticides with a WPS reference statement used on the establishment. EPA agrees that if workers, handlers, or other persons need information on a specific product that was used on the establishment, such information can be obtained using the EPA registration number and product name. In response to comments received, EPA has replaced the proposal with a requirement for the employer to retain only the EPA registration number, active ingredient(s), product name, and other application-specific information for such products, in addition to the SDS.

Similarly, EPA agrees that if they are only using a product for a single type of application it may be unnecessary to require handler employers to ensure that handlers have been trained generally on, and for specific applications have read or been informed of, all labeling requirements. The labeling could include directions for use covering multiple application methods and multiple crop sites, which may be of no relevance to a particular handler. Although the final rule continues to refer to "labeling" in this context, it now requires employers to ensure that for specific applications, handlers have read the portions of the labeling applicable to the safe use of the pesticide or have been informed in a manner they understand of all portions of the labeling applicable to the safe use of the pesticide. Further, EPA

has amended handler training to require that handlers are instructed on their duty to follow the portions of the labeling applicable to the safe use of the pesticide, and on the format and meaning of information contained on pesticide labels and in labeling.

EPA disagrees with commenters' request to distinguish between applicators who are mixing and loading pesticides and handlers who are making pesticide applications for the requirement to ensure that handlers have access to the product labeling. Regardless of the handling task being conducted (mixing, loading or applying), the handler is working with a pesticide and needs to understand and follow the applicable labeling instructions, for his or her own protection and the protection of others and the environment. A person making an application may have questions about the application rate, appropriate sites, handling precautions, practical treatment, or other information that could be found on the pesticide labeling. Therefore, EPA has chosen to retain the requirement for the employer to ensure that all handlers have access to the applicable pesticide labeling at all times during handler activities.

B. Regulating Other Persons

1. Current rule and proposal. Some provisions in the existing WPS provide protections to persons other than workers and handlers ("other persons"). For example, an existing requirement on the label and in § 170.210(a) specifies that the applicator must apply the pesticide in a way that will not contact workers or other persons. The existing requirement for entry-restricted areas on nurseries in § 170.110 specifies that an agricultural employer must not allow or direct any person, other than an appropriately trained and equipped handler, to enter or remain in the restricted area. The existing handler training content in § 170.230(c)(4) specifies that training must cover those requirements that handlers must follow, including the prohibition against applying pesticides in a manner that will cause contact with workers or other persons. The existing immediate family exemption in § 170.104(a)(2) states that the owner of the agricultural establishment must provide protections to other workers and other persons who are not part of his immediate family. The description of closed systems in § 170.240(d)(4) of the existing rule describes closed systems as systems that enclose the pesticide to prevent it from contacting handlers or other persons. Also, the scope and purpose in § 170.1 of the existing rule explains that the WPS is intended, in part, to reduce the risks of illness or injury resulting from the accidental exposure of workers and other persons to pesticides.

The proposed rule included these same protections for persons other than workers and handlers and added several additional provisions that would affect "other persons." The proposed requirement for a handler to cease or suspend application if a worker or other person is in the treated area or entry-restricted area was intended to supplement the existing "do not contact" requirements, which already protect persons other than workers or handlers. In addition, EPA proposed to include "other persons involved in the use of a pesticide to which this part applies" in the proposed anti-retaliation provision in § 170.15.

- 2. Final rule. The final rule includes the protections and references to "other persons" that were proposed, except that EPA removed the reference to other persons from the definition of closed systems. The final rule's prohibition against "other persons involved in the use of a pesticide" retaliating against workers or handlers in § 170.315 of the final rule is consistent with OSHA's non-retaliation provision. The other sections that provide protections to other persons continue existing requirements or supplement existing requirements and are discussed in detail in Unit IX. and Unit XVII.C.
 - 3. Comments and responses.

<u>Comments</u>. Many commenters, including some grower organizations, states and their organizations, a retailer organization, a few commercial applicators and two agricultural industry

organizations, opposed including protections for "other persons" in the WPS. These commenters argued that the proposal would extend the WPS to persons not currently covered and would result in an unwarranted expansion of scope beyond workers, handlers and employee/employer relationships. The grower, retailer, applicator and agricultural industry commenters stated that including "other persons" could create the potential for frivolous legal challenges by anti-chemical activists seeking to prevent pesticide applications. Many of the states and a state organization commented that pesticide labels already protect other persons so it is unnecessary to include protections for them in the WPS. Some of the states and their organizations claimed that including other persons in the WPS would complicate the implementation and enforcement of the regulations. Most of the comments focused on the proposed entry-restricted area requirements during pesticide applications in proposed § 170.105 and § 170.205, although a few commenters also opposed including "other persons" in proposed § 170.1 regarding scope and purpose, proposed §170.15 on prohibited actions, the proposed § 170.201(c)(3)(1) training requirements for handlers, the immediate family exemption in proposed § 170.301(a)(2) and the exception from some PPE when using closed systems in proposed § 170.307(d)(2).

EPA Response. EPA disagrees with the comments on including protections for "other persons" in the WPS. EPA already protects "other persons" in addition to workers and handlers in the existing WPS, so there will not be major changes to implementing and enforcing the regulations with regard to protecting "other persons" under the revised rule. EPA is not aware of anti-chemical activists using the current protections to prevent pesticide applications and the final rule does not appear significantly more likely to be used in that manner. EPA acknowledges that the labels of pesticides subject to WPS do include a statement protecting "other persons" from being contacted with pesticide either directly or through drift, because the worker protection label regulations in 40 CFR 156.200 – 156.212 require that statement. As explained in Unit IX, however, the existing requirements for an applicator to prevent pesticide contacting workers or other persons during application are insufficient because incidents where workers and other persons are sprayed still occur. As explained in Unit Section XVII.B.1, nearly all of the regulatory sections that include "other persons" are in the existing WPS. An exception is that the anti-retaliation provisions in §170.315 of the final rule (which was proposed § 170.15) prohibits retaliatory actions by an agricultural employer, commercial pesticide handler employer, or other person involved in the use of a WPS-covered pesticide, which is broader than the existing anti-retaliation provision in § 170.7(b), which cover agricultural employers and handler employers. The anti-retaliation provisions in the proposed and final regulations are modeled on similar provisions in the DOL regulations to strengthen the protections.

C. Definitions

1. General

i. Current rule and proposal. The existing WPS provides definitions for certain terms for use in the rule. In addition to the specific definitions for the twenty terms listed in 40 CFR 170.3, the WPS defines the terms "closed system," "enclosed cab," "entry-restricted area," "personal protective equipment," and "use" in other sections of the rule where those terms are used. EPA proposed to revise certain existing definitions to provide greater clarity, to add several new definitions for terms used in the rule, including definitions for the terms that had previously been defined elsewhere, and to eliminate two unnecessary existing definitions for "greenhouse" and "forest."

ii. Final rule. In the final rule, EPA has adopted the revisions to the definitions as proposed except for the definitions of the terms "agricultural establishment," "agricultural plant," "authorized representative," "closed system," "commercial pesticide handler employer," "commercial production," "employ," "enclosed space production," "entry-restricted area," "farm," "forest operation," "hand

labor," "immediate family," "labor contractor" "outdoor production," "nursery," and "use." In the final rule, EPA has deleted the definitions for the terms "greenhouse" and "forest" as proposed. EPA has also deleted the existing definitions for the terms "farm," "forest operation," and "nursery," as well as the proposed definition for "commercial production." Additionally, in the final rule EPA has added a new definition for the term "application exclusion zone." The discussions of the existing definitions and proposal, final rule, comments and EPA response for these terms are contained in Units XVIII.C.2 – XVIII.C.8. The final regulatory text for these definitions is available at 40 CFR 170.305.

iii. Comments and responses.

Comments. EPA received comments on the proposed definitions of the terms "authorized representative," "closed system," "enclosed space production," "entry-restricted area," "hand labor," "immediate family," "outdoor production," and "use". EPA did not receive any substantive comments opposed to the other proposed revisions related to definitions. EPA received several general comments from state, grower and agricultural producer associations that supported developing improved definitions because it would reduce the likelihood of alternative interpretations, while improving compliance and enforceability. Many farmworker advocacy organizations and public health organizations also supported EPA's proposed revisions to improve definitions, commenting that it is important to have clear and understandable language in order to avoid ambiguity.

During USDA's FIFRA section 25 review of the final rule, USDA commented that the definition for "agricultural plant" depends on the definition for "commercial production," and the definition for "commercial production" depends on the definition for "agricultural plant" (Ref. 15). USDA said similar issues exist in the definitions of "agricultural establishment" and "farm," "forest operation," and "nursery." USDA recommended resolving these circular dependencies. USDA also commented that the proposed definitions of "employ," "labor contractor," and "commercial pesticide handler employer" contained problematic language that could confusion as to who is ultimately responsible for providing the handler protections in Subpart F of the proposed rule.

<u>EPA Response</u>. EPA agrees that improved definitions will reduce the likelihood of ambiguity and alternative interpretations, while improving compliance and enforceability. EPA believes these proposed revisions to the definitions adopt more widely used and commonly accepted "plain English" language, and will add clarity and consistency to the rule. The proposed revisions to the definitions will also help address regulatory or policy issues with the existing rule raised by state regulatory partners and other program stakeholders.

In response to comments from USDA made during their FIFRA section 25 review of the final WPS rule, EPA agrees that the definitions for "agricultural plant" and "commercial production," and the definitions for "agricultural establishment" and "farm," "forest operation," and "nursery" are circular (Ref. 15). While EPA is not convinced that serious confusion would result, EPA has eliminated some definitions and revised others to address USDA's concern. The terms "commercial production," "farm," "nursery," and "forest operation" appear only in the definition section and are not used elsewhere in the regulation. Accordingly, EPA has deleted these definitions and merged their substantive content into the definitions of "agricultural establishment" and "agricultural plant." EPA also agrees that the current definitions of labor contractor and commercial pesticide handler employer contain some problematic language that could result in potential confusion and/or conflict regarding agricultural employer and commercial pesticide handler employer duties under the rule. In the final rule, EPA has adopted revised definitions for "employ," "labor contractor," and "commercial pesticide handler employer" to address the potential confusion that could result from conflicting language in the existing proposed definitions. EPA believes the revised regulatory text clarifies that CPHEs are responsible for the handlers they

employ and agricultural employers would no longer be considered employers of CPHE handlers for the purposes of the WPS, without overlooking the fact that some handlers are hired by agricultural employers through labor contractors and not CPHEs. A copy of USDA's comments and EPA's responses is available in the docket for this rulemaking. (Ref. 15).

2. Authorized Representative.

i. Current rule and proposal. The existing WPS does not contain a definition for "authorized representative." EPA proposed to add the term "authorized representative" to the rule and defined it as "a person designated by the worker or handler, orally or in writing, to request and obtain any information that the employer is required to provide upon request to the worker or handler."

ii. Final rule. The rule finalizes the proposed definition with changes. EPA has retitled the term "authorized representative" to "designated representative" to better describe the relationship between the representative and the worker or handler, and the definition narrows the information that is required to be provided by the employer to the designated representative. In the final rule, "designated representative" means "any persons designated in writing by a worker or handler to exercise a right of access on behalf of the worker or handler to request and obtain a copy of the pesticide application and hazard information required by § 170.309(h) in accordance with § 170.311(b) of this part."

iii. Comments and responses.

Comments. EPA received many comments from states, growers, agricultural associations and pesticide manufacturer associations objecting to the definition of "authorized representative." Most commenters objected to the proposed requirement for employers to make certain pesticide information available to an "authorized representative" of their workers or handlers rather than the actual definition of authorized representative. Several farm bureau commenters and grower groups stated that oral designation of the representative could result in abuse, and would be unenforceable. One comment from a farmworker advocacy organization stated that EPA should keep the definition for authorized representative and clarify the range of representatives that could legitimately be asked to receive information on behalf of a worker or handler (e.g., medical care provider, legal advocate, family member, etc.).

<u>EPA Response</u>. EPA has been convinced by comments that designation of the representative must be in written form to protect employers from fraudulent claims. A written request that identifies the worker or handler can be verified against employment records, and information about the dates of their employ can be used to narrow the information needed to be provided. The final rule requires employers to respond to written requests.

EPA disagrees with the recommendation to limit the definition to certain persons that could be asked to request the information on behalf of the worker or handler. EPA believes that specifying classes of persons permitted to serve as designated representative would unnecessarily limit worker and handler access to needed information. The final rule requires employers to respond to such requests within 15 days. However, to ensure that medical personnel treating a worker or handler have timely access to information necessary for purposes of diagnosis or treatment, EPA has included a separate requirement for employers to promptly provide the information to treating medical personnel or those working under their direction, at 170.311(b)(8).

3. Closed System

i. Current rule and proposal. The existing WPS defines the term "closed system" as "a system that encloses the pesticide to prevent it from contacting handlers or other persons." EPA proposed to move the definition of closed system to the definition section of the rule and to redefine a closed system as "a system for mixing or loading pesticides that encloses the pesticide during removal of the

pesticide from its original container and transfer, mixing, or loading of the pesticide product, mixtures or dilutions, and any rinse solution, if applicable, into a new container or application equipment, in such a manner that prevents the pesticide and any pesticide mixture or use dilution from contacting handlers or other persons before, during and after the transfer, except for negligible release associated with normal operation of the system."

ii. Final rule. In the final rule, EPA has defined "closed system" as "an engineering control used to protect handlers from pesticide exposure hazards when mixing and loading pesticides." The final regulatory text for this definition is available at 40 CFR 170.305.

iii. Comments and responses.

<u>Comments</u>. EPA did not receive any specific comments on the definition of closed system. However, EPA received a number of comments related to EPA's proposal on closed systems that indicated the proposed requirements may be too prescriptive or limiting, could eliminate desired flexibility for growers, and could discourage innovation and the adoption of closed systems.

<u>EPA Response</u>. EPA agreed with the comments that the proposed requirements related to closed systems may be too prescriptive or limiting, could eliminate desired flexibility for growers, and could discourage innovation and the adoption of closed systems. Although the comments did not specifically mention the closed system definition, EPA reconsidered the proposed definition of closed system in light of the overall comments on closed system requirements. EPA believes that a broader definition of "closed system" will encourage industry innovation better than the proposed prescriptive definition, and will retain flexibility for handler employers to design systems specific to their needs. In the final rule, EPA has adopted a new definition of closed system that more accurately defines the nature and intent of a closed system without inadvertently prescribing specific requirements and operational components for such closed systems.

4. Enclosed Space Production and Outdoor Production.

i. Current rule and proposal. The existing WPS does not contain definitions for the terms "enclosed space production" or "outdoor production." Instead, the existing WPS defines the term "greenhouse" to describe the type of WPS-covered agricultural establishments that produce agricultural plants inside enclosed structures. The existing rule uses the terms "farm," "forest" and "nursery" for WPS-covered agricultural establishments that produce agricultural plants outdoors. Greenhouse is defined in the existing WPS as "any operation engaged in the production of agricultural plants inside any structure or space that is enclosed with nonporous covering and that is of sufficient size to permit worker entry. This term includes, but is not limited to, polyhouses, mushroom houses, rhubarb houses, and similar structures. It does not include such structures as malls, atriums, conservatories, arboretums, or office buildings where agricultural plants are present primarily for aesthetic or climatic modification." EPA proposed to delete the definition of "greenhouse" because it would no longer be necessary as a result of the proposed addition of a new definition for "enclosed space production." EPA proposed to define enclosed space production as "production of an agricultural plant in a structure or space that is covered in whole or in part and that is large enough to permit a person to enter." EPA also proposed to add a new definition for the term "outdoor production" and defined it as "production of an agricultural plant in an outside open space or area that is not enclosed or covered in any way."

ii. Final rule. In the final rule, EPA has deleted the definition of the term "greenhouse" as proposed, and has adopted the definitions for "enclosed space production" and "outdoor production" with modifications. The final rule defines "enclosed space production" as "production of an agricultural plant indoors or in a structure or space that is covered in whole or in part by any nonporous covering and that is large enough to permit a person to enter," and defines "outdoor production" as "production"

of an agricultural plant in an outside area that is not enclosed or covered in any way that would obstruct the natural air flow." The final regulatory text for these definitions is available at 40 CFR 170.305.

iii. Comments and responses.

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Comments. EPA received several comments from states and their organizations opposing the definition of "enclosed space production" as written. A few other commenters also expressed concerns with the definition of "outdoor production." A state association noted that the proposed definition could greatly expand areas covered under certain entry restrictions to include any covered area such as fields or groves with shade covers and/or screen houses. The commenter expressed concerns that entry restrictions currently applicable to greenhouses would be extended to these establishments, and is not aware of any need for such an extension of these restrictions. States generally echoed these comments. One state requested clarification of whether the term "spaces covered in part" includes structures such as "hoop houses," and another state noted that the proposed rule did not define or reference high tunnels and requested clarification of whether "high tunnels" are considered a greenhouse for the purposes of WPS (i.e., would "high tunnels" be considered a type of enclosed space production?). One state commented that the proposed definition expands areas covered under certain entry restrictions to include shade houses and screen houses and this would have a major impact in on the state's nursery industry. Another state also expressed concerns that the proposed definition of enclosed space production would expand restrictions beyond greenhouses, and suggested that EPA add the phase "where the production of agricultural plants for research or commercial purposes occurs" to the definitions of enclosed space production and outdoor production so that only those operations engaged in the production of agricultural plants for commercial purposes would be covered by the WPS. Another state commented that the term "outdoor production" is too broad and by misinterpretation, could encompass a number of non-farm activities.

During USDA's FIFRA section 25 review of the final rule, USDA commented that the inclusion of the term "natural forest" in the definition of "outdoor production" creates confusion since there is no explanation of what the term "natural forest" means and therefore the term is not needed (Ref. 15).

EPA Response. EPA considered the comments submitted and agrees with the comments that said the proposed definition of "enclosed space production" could expand areas covered under certain entry restrictions to include any covered area such as fields or groves with porous shade covers and/or screen houses where such restrictions are not necessary. EPA noted the potential impact of the proposed definition on the nursery industry as raised by commenters. EPA also agrees that the proposed definition of "outdoor production" could lead to some outdoor production being considered enclosed space production because of the phrase "that is not enclosed or covered in any way." EPA is convinced that the definition of enclosed space production and outdoor production should be revised so that operations that use non-porous coverings in their plant production operations, such as screen houses and shade houses, are not covered by the entry restrictions deemed necessary for the protection of workers and handlers that are working with pesticides or in pesticide treated areas in enclosed space production operations. Therefore, EPA revised the definitions of enclosed space production and outdoor production to clarify that enclosed space production only includes areas covered in whole or in part "by any nonporous covering," rather than "any covering" as in the proposed definition; and that outdoor production will include areas that are covered only with coverings that are sufficiently porous that they do not obstruct the natural air flow typical of open fields or forests. It is intended that these definitions of enclosed space production and outdoor production be complementary, such that all production agriculture is either enclosed space production or outdoor production.

EPA does not agree with the request to add the phrase "where the production of agricultural

plants for research or commercial purposes occurs" to the definitions of enclosed space production and outdoor production so that only those operations engaged in the production of agricultural plants for commercial purposes would be covered by the WPS. EPA believes other definitions and language in the rule already clearly limit the scope of the WPS to establishments where the production of agricultural plants for research or commercial purposes occurs, so the addition of such language to these definitions would be redundant and would not serve to further limit the scope of the rule in any way not already accomplished through other means.

Some commenters requested clarification of whether structures such as "hoop houses," and "high tunnels" are considered a type of enclosed space production. The term "greenhouse" in the WPS has resulted in enforcement problems, because of the extreme variability in the types of structures that might be considered greenhouses. This problem is compounded when considering the many greenhouse-type structures (e.g., polyhouses, mushroom houses, hoop houses, high tunnels and similar structures) that have come into use. This is why EPA has replaced the term greenhouse with enclosed space production. EPA believes the new terms correspond more accurately to the nature of the risk that EPA is concerned about mitigating (i.e., use of pesticides in enclosed spaces that could affect pesticide inhalation exposure potential). Therefore, if a structure or space is covered in whole or in part by any nonporous covering and is large enough to permit a person to enter, then the structure or space would fall under the definition of enclosed space production in the final rule. EPA anticipates that most greenhouses, hoop houses, high tunnels and similar structures will fall within the definition of enclosed space production, but a final determination will be made on a case-by-case basis applying the parameters of the definition to each situation.

EPA agrees with USDA that the inclusion of the term "natural forest" in the definition of "outdoor production" creates confusion and is not needed. In response, EPA has revised the final definition of outdoor production accordingly (Ref. 15).

- 5. Entry-Restricted Area and Application Exclusion Zone.
- i. Current rule and proposal. The existing WPS does not contain a definition for the terms "entry-restricted area" or "application exclusion zone." Under the existing rule, the term "entry-restricted area" is used to refer to areas on an establishment from which workers and other persons must be excluded during, and/or immediately after, an ongoing pesticide application to protect the workers or other persons from being contacted by the pesticide (either directly or through drift). EPA proposed to define the term "entry-restricted area" as "the area from which workers or other persons must be excluded during and after the pesticide application."

ii. Final rule. In the final rule, EPA has added the term "application exclusion zone" instead of the proposed term "entry-restricted area." EPA has defined the term "application exclusion zone" as "the area surrounding the application equipment which must be free of all persons, other than appropriately trained and equipped handlers, during pesticide applications." The final regulatory text for this definition is available at 40 CFR 170.305.

iii. Comments and responses.

<u>Comments</u>. EPA received several comments from states regarding the term "entry-restricted area." One commenter said the term was linguistically awkward and said EPA should instead use the term "restricted area buffer."

<u>EPA Response</u>. EPA considered the comments submitted and agrees with the comments that the term "entry-restricted area" was not clear and would be likely to cause confusion. In the final rule, EPA has eliminated the use of that term and has therefore deleted the proposed definition. The final rule adopts the term "application exclusion zone" to refer to the area from which persons must be excluded

during applications. See Unit IX. for EPA's response to the comments on the WPS requirements related to entry-restricted areas.

6. Hand labor

i. Current rule and proposal. The existing WPS defines hand labor as "any agricultural activity performed by hand or with hand tools that causes a worker to have substantial contact with surfaces (such as plants, plant parts, or soil) that may contain pesticide residues. These activities include, but are not limited to, harvesting, detasseling, thinning, weeding, topping, planting, sucker removal, pruning, disbudding, roguing, and packing produce into containers in the field. Hand labor does not include operating, moving, or repairing irrigation or watering equipment or performing the tasks of crop advisors." In the proposal, EPA intended to revise the definition by deleting the following sentence from the existing definition, "These activities include, but are not limited to, harvesting, detasseling, thinning, weeding, topping, planting, sucker removal, pruning, disbudding, roguing, and packing produce into containers in the field." In the proposed regulatory text for the definition of term "hand labor," EPA inadvertently deleted the phrase "except that hand labor does not include operating, moving, or repairing irrigation or watering equipment or performing crop advisor tasks" from the end of the definition. The erroneously proposed definition for the term "hand labor" was "any agricultural activity performed by hand or with hand tools that cause a worker to have substantial contact with plants, plant parts, or soil and other surfaces that may contain pesticide residues."

ii. Final rule. EPA has corrected the unintentional omission from the proposed definition of "hand labor." The final rule defines "hand labor" as "any agricultural activity performed by hand or with hand tools that cause a worker to have substantial contact with plants, plant parts, or soil and other surfaces that may contain pesticide residues, except that hand labor does not include operating, moving, or repairing irrigation or watering equipment or performing crop advisor tasks." The final regulatory text for this definition is available at 40 CFR 170.305 for the final regulatory language for definitions.

iii. Comments and responses.

<u>Comments</u>. One commenter objected to the proposed change to the definition of hand labor that deleted the phrase "except that hand labor does not include operating, moving, or repairing irrigation or watering equipment or performing crop advisor tasks" from the end of the definition. The commenter indicated that removing this exception from the definition of hand labor would make the irrigation exception for early entry unworkable and would disrupt irrigation operations.

<u>EPA Response</u>. EPA agrees with the comment on the definition of "hand labor." In the final, rule EPA has deleted the sentence listing hand labor activities as proposed, but has retained the clause excluding "operating, moving, or repairing irrigation or watering equipment or performing crop advisor tasks" from being considered hand labor tasks

7. Immediate Family. See Unit XVII.A. for a complete discussion of EPA's consideration of the definition of "immediate family" in conjunction with the exemption from certain provisions of the WPS for owners and members of their immediate families.

8. Use

i. Existing definitions and proposal. The existing WPS provides a definition of the term "use" (as in "to use any registered pesticide in a manner inconsistent with its labeling") for the purposes of the rule at 40 CFR 170.9, "Violations of this part." For the purposes of the WPS, EPA has interpreted the term "use" to cover a broad range of pesticide-related activities that are listed at 40 CFR 170.9. EPA proposed to move the existing definition for "use" found at 40 CFR 170.9 into the definitions section of the rule.

ii. Final rule. In the final rule, EPA has adopted the definition for "use" as proposed. The final regulatory text for this definition is available at 40 CFR 170.305.

iii. Comments and responses.

Comments. EPA received several comments from states, growers, agricultural associations and pesticide manufacturer associations objecting to the proposed definition of "use." Most commenters objected to the definition of use because they did not support inclusion of "arranging for application of the pesticide" as part of the definition of "use." Some commenters said they believed that this language would greatly expand the scope of the WPS and would be unreasonable and unnecessary. Some commenters noted that they could not see how "arranging for application of the pesticide" could be considered use. During its review of the draft final rule under FIFRA section 25(a), USDA noted that the term "arranging for the application of the pesticide" as part of the definition of the term "use" could lead to persons that call on or answer the telephone and "arrange" for pest management by scheduling the appointment on behalf of another to be covered by the rule and possibly have WPS responsibilities.

EPA Response. EPA disagrees with comments that say the proposed definition for the term "use" could or will expand the scope of the WPS because this interpretation has been in the WPS since the rule first became effective. Moreover, EPA has not been made aware of any instances where this interpretation of "use" has resulted in an unreasonable or inappropriate outcome. EPA believes that "arranging for application of the pesticide" is appropriately part of the definition of "use" for the purposes of the WPS because in production agriculture, the individual who physically "uses" a pesticide almost always does so at the direction of another person who has substantially greater control over the circumstances of the use. Thus the WPS is designed so that when an agricultural or handler employer arranges for the application of a pesticide by a handler employee, it triggers certain WPS duties that are properly the responsibility of the agricultural or handler employer. For instance, once the agricultural employer arranges for a pesticide application by a commercial pesticide handling establishment, the commercial pesticide handler employer must provide the agricultural employer with certain information about the intended application before the application takes place (so the employer will be able to fulfill WPS notification requirements and protect workers during application, etc.). In such circumstances, it is reasonable and appropriate that the handler employer should be held responsible for the preapplication information exchange even though the application has not commenced and even though the handler employer personally never physically "uses" the pesticide.

EPA interprets "arranging for application of the pesticide" as used in § 170.9(a) and § 170.305 as a means of assuring that the entities (generally the agricultural employer or handler employer) with the most authority and control over WPS compliance would be legally responsible for WPS compliance. EPA does not interpret "arranging for application of the pesticide" as making subordinate persons who merely perform the clerical functions of arranging for application of the pesticide liable for WPS compliance. Therefore, since EPA has not been made aware of any instances where the existing interpretation of the term use has resulted in any problems for growers, states or the agricultural industry, EPA has moved the definition for the term "use" into the definitions section of the rule without any change from the proposal.

D. Restructuring 40 CFR part 170

1. Current rule and proposal. The existing WPS is organized into three subparts: "General Provisions," "Standard for Workers," and "Standard for Handlers." Content that applies to both workers and handlers is repeated creating redundancy throughout the rule.

EPA discussed renaming the regulation "Requirements for Protection of Agricultural Workers and Pesticide Handlers" in the preamble of the proposal and proposed reorganizing the rule into four

subparts: "General Provisions," "Requirements for Protection of Agricultural Workers," "Requirements for Protection of Pesticide Handlers," and "Exemptions and Exceptions." EPA proposed creating the "General Provisions" subpart to describe certain obligations for agricultural employers, handler employers, and those requirements that apply to both. The proposal included subparts "Requirements for Protection of Agricultural Workers" and "Requirements for Protection of Pesticide Handlers" to provide information that supplements the general duties and obligations for employers and to outline the content of the training and decontamination supplies that the employer must provide for workers and handlers respectively. EPA proposed to consolidate most of the exceptions and exemptions into a separate subpart titled "Exemptions and Exceptions" to make them easier to find and reference.

2. Final Rule. In the final rule, EPA has retained the existing name of the regulation, "Worker Protection Standard," and has adopted the proposed restructuring of the rule with minor modifications.

EPA has determined that it is appropriate to allow one year for employers, trainers, and state and tribal regulators to prepare for the changes to the WPS. See Unit XIX. In order to allow the existing WPS to remain in effect for one year and to make available the revised regulatory language in advance of the implementation date, both the existing WPS and the revised WPS must appear in the Code of Federal Regulations. Thus the final rule provides that Subparts A, B and C of part 170 will remain in effect until one year after the effective date of this final rule. Subparts D, E, F and G of part 170 contain the full text of the revised WPS; however, these subparts will not be implemented until one year after the effective date of this final rule. Some provisions of subparts D, E, F and G, such as pesticide safety training and the pesticide information display, will not be implemented until two years after the effective date of this final rule. One year after the effective date of this final rule, subparts A, B and C will no longer be effective. At that time, EPA intends to delete subparts A, B and C from part 170.

In addition to finalizing the proposed structuring of the rule, EPA has added a new section providing a process for allowing states and tribes to request equivalency determinations from EPA for existing state or tribal laws or regulations that may provide protections equivalent to the WPS. EPA has added this to a retitled subpart: "Exemptions, Exceptions and Equivalency."

3. Comments and responses.

<u>Comments</u>. EPA did not receive any comments opposed to the proposal to restructure the WPS. One commenter noted that the proposed restructuring of the rule increased the clarity of the rule and the relationship among the components. Another commenter asserted that there was no need to change the name of the regulation, and noted that if EPA was going to change the name of the rule, it should more accurately represent the full scope of the rule and the impacted establishments.

<u>EPA Response</u>. EPA agrees with the comment that it is unnecessary to change the name of the rule. "Worker Protection Standard" and the abbreviation WPS are commonly used and associated with the rule. Upon further consideration, EPA agrees that the existing name of the rule is very widely recognized and that it will facilitate more effective communications on the rule to retain the current name of the rule.

EPA also agrees with the commenter that the proposed restructuring of the rule increases the clarity of the rule and the relationship among the components. EPA is adopting the proposed restructuring of the WPS in the final rule with the minor modifications noted. EPA expects the revised part 170 will be easier to read and understand, thereby improving compliance by worker and handler employers.

4. Costs and benefits. EPA does not estimate any costs associated with the restructuring of the rule. The benefits of the restructuring will be increased clarity and understanding of the rule which should result in improved compliance and more consistent enforcement.

E. Equivalency Provisions

- 1. Current rule and proposal. The current WPS does not contain equivalency provisions that would permit EPA to potentially recognize, through a WPS-established regulatory mechanism, state or tribal worker protection laws and/or regulations that may provide equivalent or significantly greater protection in comparison to the provisions of the existing WPS, or provide equivalent protection at a significantly lower cost. EPA did not propose to add equivalency provisions to the rule because it did not receive information from states or tribes that such provisions were necessary, and had not been informed by growers that WPS requirements conflicted with existing state or tribal worker protection laws or regulations.
- 2. Final rule. In the final rule, EPA has included a section on equivalency because of comments received that indicate provisions may be needed to address certain issues with the WPS potentially conflicting with existing state and tribal worker protection laws or regulations. EPA recognizes that some states and tribes have existing worker protection provisions in their own laws and regulations that may be equivalent to the provisions of the existing WPS, that may provide significantly greater protection, or may provide equivalent protection at a significantly lower cost, and decided it would be more practical and efficient to establish a mechanism to evaluate specific state or tribal requirements and to make equivalency determinations rather than relying on other EPA enforcement mechanisms or policies to be able to allow such determinations. The final regulatory text for this requirement is available at 40 CFR 170.609.

3. Comments and responses.

Comments. Although EPA did not propose equivalency provisions, EPA received comments from the California Department of Pesticide Regulation (CDPR) that indicated it would be beneficial if states could be granted 'equivalency' as was done for the current WPS. The CDPR comment refers to an independent enforcement discretion decision that was granted under the current WPS to recognize CDPR's requirement for the content of their field posting sign to be equivalent to the existing requirement at 40 CFR 170.120. Comments from some other state pesticide regulatory agencies indicate there may be issues of equivalency between their regulations and the final WPS requirements. Although these commenters did not specifically raise the need for equivalency provision, they indicated a need for EPA to be aware of the issue and potentially identify solutions.

EPA Response. Based on the comments received and EPA's experience with the current WPS and requests from CDPR for equivalency on certain regulatory requirements, EPA agrees that there are potential situations where states or tribes may request EPA to consider equivalency under the WPS for their laws or regulations. Therefore, EPA believes it is prudent to consider an equivalency process under the WPS, and feels strongly that it is more efficient and advantageous to establish a mechanism for considering equivalency in the WPS rule rather than relying on other mechanisms. EPA has provided a general equivalency process in the rule that is modeled on the provisions that were developed and implemented for substantially the same reason and purpose under the pesticide containment regulations in 40 CFR 165.97. (71 FR 47330, August 16, 2006).

F. Clarifications

- 1. Scope and Purpose. In the final rule, EPA has clarified who the rule protects and that agricultural and commercial pesticide handler employers are responsible for carrying out the requirements of the rule. EPA has also clarified that handlers have responsibilities under the rule to protect workers and other persons during pesticide applications. Refer to 40 CFR 170.301 for the revised language.
 - 2. Applicability. In the final rule, EPA has clarified in 40 CFR 170.303(c) that users must comply

with product labeling requirements where the labeling requirements differ from the rule, except as provided in 40 CFR 170.601, 170.603, and 170.607, where the WPS provides exceptions to label-required PPE and REIs.

G. Anti-retaliation Measures

The purpose of the requirements discussed in this section are to protect a worker's or handler's right to pursue protections established by the WPS without fear of retaliation from their employer. Retaliation occurs when an employer takes an adverse action against a worker or handler because he or she engaged in an activity protected by the law.

1. Current rule and proposal. The existing WPS includes three related requirements intended to protect workers and handlers from retaliation. The prohibited actions section of the existing WPS directly prohibits agricultural employers from taking "any retaliatory action for attempts to comply" with requirements of the rule but does not describe what those actions include. The existing rule also requires employers to assure that workers and handlers are informed, as part of their pesticide safety training, about the availability of pesticide specific information and that they have protection against retaliatory acts for attempting to comply with the rule.

EPA proposed modifications to the anti-retaliation provision to clarify the actions that are prohibited. The proposed rule also expanded the training to highlight the anti-retaliation provisions of the WPS.

2. Final rule. The anti-retaliation measures proposed have been modified in the final rule._EPA has modified the anti-retaliation provision based on comments provided from DOL on how EPA could improve its retaliation provision by modeling it after language used in similar provisions in DOL regulations. Moreover, EPA notes that this rule does not preempt the general anti-retaliation provision in the DOL-administered Occupational Safety and Health Act, 29 U.S.C. 660(c). The final regulatory text for the anti-retaliation provision is available at 40 CFR 170.315. The expanded training points intended to address protection from retaliation were finalized as proposed. The final regulatory text for the expanded training points is available at 40 CFR 170.401.

3. Comments and responses.

<u>Comments.</u> Many commenters, including 71 Members of Congress, farmworker advocacy organizations, Unions, Legal Aid organizations and private citizens stated that the existing language in the WPS does not provide strong enough protections against retaliation for workers to feel safe asking for information about pesticide applications, protective equipment or other protections required under the WPS. Commenters noted that farmworkers are also afraid to report violations or file a complaint with the employer or state pesticide regulatory agency because they fear the loss of their jobs or other forms of retaliation. These commenters specifically asked EPA to adopt the same standard provided by OSHA for employees to report unsafe working conditions and protect employee confidentiality.

Many state regulatory agencies, grower associations, and farm bureaus opposed the antiretaliation measures as unnecessary, asserting the proposed requirements do not provide any additional protection. State regulatory agencies specifically objected to including "other persons" in the prohibited actions on the grounds that the definition is unclear and would result in overly burdensome investigations. Other state pesticide regulatory agencies noted that retaliation investigations are beyond the scope of pesticide use inspections and inspector training.

<u>EPA Response</u>. EPA understands the importance of establishing mechanisms for farmworkers to get hazard information about their workplace, to request protections required under the WPS, or to file complaints about workplace practices with their employer or a regulatory agency without risk of

retaliation. The Agency disagrees with commenters that assert anti-retaliation provisions provide no additional protections.

EPA recognizes the value of allowing workers to maintain confidentiality when requesting information or filing complaints against employers and would refer anonymous tips or complaints about workplace safety to the appropriate state enforcement agency. However, unlike the OSH Act, FIFRA does not include a directive to ensure confidentiality for workers, handlers, or other complainants. The OSH Act specifically establishes a worker's right to file a complaint with OSHA about safety or health hazards in their workplace and to request that their names not be revealed to their employer. EPA can, and typically does, protect tips, complaints, inspection reports, etc., as "enforcement confidential." Although this is not an absolute protection, EPA typically continues to treat such information as confidential until an enforcement case is underway. In addition, a number of states have established laws or policies that direct inspection and enforcement personnel to maintain confidentiality of any farmworkers who files a complaint.

EPA recognizes the potential burden on state pesticide regulatory agencies of investigating complaints and understands that proving retaliation claims is different than other pesticide use violations. If retaliation is suspected or reported, EPA encourages state regulatory agencies to refer investigations to EPA, or cooperate in the investigation of retaliation claims with another appropriate regulatory agency.

H. Comments Related to OSHA

Comments. Many commenters suggested that EPA ensure that the WPS provides workers and handlers with protections comparable to those provided to workers in other hazardous occupations under OSHA. Commenters suggested that EPA increase requirements for safety training, decontamination, emergency assistance, PPE (respirator safety), medical monitoring, and information about chemicals being used in the workplace to match OSHA's requirements. More specifically, many commenters suggested that EPA require annual training for workers and full pesticide safety training before workers and handlers are directed to work with pesticides or in pesticide-treated areas. Some commenters suggested that EPA require an emergency shower within the work area for immediate emergency use where there is potential for the eyes or body of any person to contact pesticides and adopt OSHA standards related to eyewash stations. Further, they urged EPA to adopt OSHA requirements related to the timing of providing transportation to employees in the event of a known or suspected pesticide exposure or injury. Many commenters expressed support for EPA's adoption of OSHA's standards for respiratory protection. Many commenters requested that EPA adopt medical monitoring for handlers exposed to cholinesterase-inhibiting pesticides. Some commenters suggested that EPA require records to be retained for 30 years and employers to maintain a written hazard communication plan, as required under OSHA regulations. Some commenters requested that EPA adopt OSHA's standards for confined spaces for early-early entry workers. Many commenters suggested that EPA adopt OSHA's anti-retaliation provisions to allow workers and handlers to report suspected violations of the WPS without fear of losing their jobs.

Many commenters raised general concerns that incorporating into the WPS by reference elements of OSHA's regulations, i.e., some portions of the respirator standards at 29 CFR 1910.134, would constitute an expansion of OSHA's jurisdiction.

<u>EPA Response</u>. EPA appreciates the commenters' suggestions about incorporating OSHA-equivalent protections into the WPS. For comments and EPA's responses related to specific areas of the proposal, please see the appropriate sections of this document.

EPA has addressed concerns about jurisdictional issues related to the incorporation by reference of some of OSHA's respiratory protection standards in Unit XV.A.

XIX. Implementation

A. Proposal. EPA proposed to make the final rule effective 60 days after the date of publication in the Federal Register; however, compliance with certain provisions, including the additional content of pesticide safety training and pesticide safety information, and new signs for posting, would not be required until 2 years after the effective date of the final rule. EPA proposed the 2-year delay between effective date of the final rule and the implementation date to allow time for new training materials to be developed and made available, and to give employers, trainers, and other affected stakeholders time to make the necessary changes to their practices and operations to comply with the new training and pesticide safety information requirements. EPA also linked the implementation date for the revised pesticide safety training requirements for workers and handlers to the availability of new revised training materials that satisfy the new rule requirements. Under the proposal, if EPA announced the availability of such materials sooner than 18 months after the effective date of the final rule, then the new training requirements would go into effect 2 years after the effective date of the final rule. If EPA announced the availability of materials that comply with the requirements more than 18 months after the effective date of the final rule, then the new training requirements would not take effect until 180 days after the announcement of availability of complying training materials published in the Federal Register.

B. Final rule. EPA has included in the final rule a one-year delay from the effective date of the final rule before employers must comply with any of the new WPS requirements. Thus, on [insert date one year and 60 days after the date of publication in the Federal Register], employers will be required to comply with almost all of the new and revised WPS requirements. However, employers will not be required to comply with certain new WPS provisions until two years after the effective date of the final rule. This two year delay applies to the new requirements for pesticide safety training for workers and handlers, pesticide safety information and handlers to suspend applications when workers or other persons are in the application exclusion zone. As proposed, the final rule provides that compliance with certain new training requirements will not be required until the later of two years after the effective date of the final rule, or 180 days after EPA publishes in the Federal Register a notice of availability of new revised training materials that satisfy the new rule requirements.

The final regulatory text for these provisions is available at 40 CFR 170.2, 170.311(a)(3), 170.401(c)(3), 170.501(c)(3) and 170.505(b).

C. Comments and responses.

<u>Comments</u>. Most comments that addressed implementation focused on three main areas: 1) The need for better and more effective enforcement of the revised rule once the new requirements are effective; 2) the need for appropriate supporting communication, education, training and compliance assistance materials to facilitate effective implementation; and 3) the need for additional time before the final rule becomes effective to give regulators and the regulated community time to prepare for compliance with new requirements.

Many comments from states, pesticide safety educators, trainers, grower associations and pesticide manufacturer associations pointed out a need for appropriate training and compliance assistance materials to support effective implementation. Commenters indicated that it was essential for EPA to have updated communications and compliance assistance materials, such as fact sheets and the "WPS How to Comply" manual, developed and available to all affected parties in order for the regulated community to be able to learn and understand new requirements. Several states, grower

associations and pesticide manufacturer associations commented that EPA should provide more time before the new rule requirements become effective so that regulators and the regulated community can more adequately prepare for compliance with new requirements. However, several farmworker advocacy organizations urged EPA to implement the proposed training requirements for workers and handlers sooner than the proposal of 2 years from the effective date of the final rule.

EPA Response. EPA considered the comments submitted and agrees that after publication of the final rule, some time is needed before the new WPS requirements are implemented. EPA understands that State, tribal and federal regulators need time to become familiar with the new regulation, provide training to pesticide inspectors, develop the capacity for enforcing the new rule requirements, establish appropriate WPS inspection and enforcement policies, and conduct outreach to the regulated and protected communities. In addition, agricultural employers will need time to become familiar with the new requirements and implement any necessary changes. In the final rule, EPA has delayed the implementation of the new WPS requirements for one year so that EPA can work with state and tribal pesticide regulators and the regulated community to better prepare for compliance with new rule requirements. The existing rule will remain in effect and be enforced during this time, as provided in 40 CFR 170.2.

EPA disagrees with comments that the compliance dates for the new worker and handler training requirements should be implemented sooner than 2 years from the effective date of the final rule as outlined in the proposal. EPA believes that up to 18 months could be needed in order to develop and disseminate new, high quality, multi-lingual worker and handler training materials in multimedia formats that comply with the new requirements. Additionally trainers will have to obtain the new training materials, become familiar with the new training content and ensure that they continue to meet any eligibility requirements to train. Therefore, EPA has decided to retain the proposed requirement to delay the new training requirements for 2 years from the effective date of the final rule (or 180 days after the announcement that training materials are available, whichever is later) to allow adequate time for development and widespread distribution of the materials to trainers and employers. While EPA agrees that it is important for workers and handlers to have the new safety training information as soon as possible, time will be needed to create and distribute new training materials and to allow existing trainers to familiarize themselves with those new materials. In order to maximize compliance with the final rule, and in the interests of consistency and efficiency, EPA intends to develop and make available suitable training materials. EPA intends to have new training materials developed and disseminated as soon as practical and will encourage employers to begin using the new materials as soon as they become available so that many workers and handlers will begin receiving the benefits of the new training before the required date.

EPA is committed to a robust outreach, communications and training effort to communicate the new rule requirements to affected WPS stakeholders. To facilitate implementation, EPA plans to issue plain language "how to comply" fact sheets and guidance materials once the final rule is published. EPA plans to develop compliance assistance materials that are targeted to specific agricultural sectors and rule requirements such as respirator requirements or the WPS exemptions and exceptions. EPA also intends to develop and disseminate new worker and handler training materials, conduct outreach to potentially affected parties, and provide assistance and resources to States and Tribes for WPS implementation. EPA plans to hold Pesticide Regulatory Education Program courses for State and Tribal pesticide program staff that will focus on WPS implementation, and Pesticide Inspector Residential Training courses for State and Tribal pesticide inspectors that will focus on WPS inspection requirements.

XX. Economic Analysis

A. Cost Assessment and Related Topics

1. Estimation of Costs

<u>Comment</u>. EPA has underestimated the cost of the proposed rule. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0205, #1642, #1722, #1870, #2155, #2199, #2200, #2207, #2208, #2209, #2225, #2238, #2239, #2242, #2252, #2258, #2269, #2282, #2293, #2303, #2304, #2310, #2319, #2376, #2385, #2432, #2491, #2492)

<u>EPA Response</u>. EPA appreciates the comment, but without additional information is unable to determine how the estimated cost should be modified. In some cases, it appears that commenters observed the reported \$5 per worker and \$60 per handler costs reported in the evaluation of the impacts on jobs and did not realize that these costs represent only the portion of the costs accruing for each employee; establishments will also bear certain costs less directly associated with the number of employees. For example, posting hazard information is required if workers are present, regardless of the number of workers on the establishment. In other cases, it appears that commenters confused the requirements for obtaining certification to use restricted use products with the handler training requirements under the Worker Protection Standard (WPS).

<u>Comment</u>. EPA has underestimated the number of affected entities by 1) not counting contract labor; 2) failing to count diversified and livestock operations; 3) underestimating overall numbers of workers, including contract labor, by using outdated (2007 Census of Agriculture) data, rather than the most recent available (2012 Census of Agriculture); 4) failing to use current wage rates; 5) failing to account for the seasonality of farm worker employment. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2200, #2206, #2286, #2294, #2439, #2442)

EPA response. EPA disagrees that there has been an underestimation of affected entities. 1) While the estimates of the numbers of entities and workers in EA for the proposed rule did not specifically include contract labor, EPA relied on employment figures in the 2007 Census of Agriculture. These figures include all employees, including those who are not engaged in hand labor activities nor handle pesticides, and counts a person multiple times if employed at multiple establishments. As a result, the number of affected workers was likely overestimated for the analysis of the proposed rule. For the EA for the final rule, EPA relied on the 2012 Census of Agriculture, which resulted in an estimate of almost two million workers. Relying on more detailed surveys of farm labor, USDA estimates that there are just over one million workers, including 200,000 workers employed through contract services. This indicates that EPA has overestimated the number of workers, and probably the number of entities, that are affected by the final rule. 2) Using a special tabulation of data from the 2007 Census of Agriculture, EPA specifically accounted for livestock operations (NAICS 112) that produce crops in the analysis of the proposed rule and used the information to estimate the number of livestock operations producing crops for analysis of the final rule. 3) For the final rule, EPA has used data from the 2012 Census of Agriculture, which was not published prior to the publication of the proposed rule. 4) For the final rule, EPA has updated wages and prices to estimate costs using data from 2014. 5) The seasonality of farm worker employment leads to an overestimation of cost because EPA has assumed that all workers are present on a farm for the entire season. This means, for example, that EPA assumes farms are required to notify all workers of all pesticide applications when, due to seasonal employment, workers may not be present for most applications and notifications are not required.

<u>Comment</u>. The National Cotton Council believes that EPA has significantly underestimated the costs to farmers that these additional regulations will impose. For example, EPA estimates a cost of \$5/worker/year. The wages alone for a four-hour training session – even at the current federal

minimum wage – would be \$29/worker and that does not include transportation or fees for the training. Additional costs to farmers would include signs and postings, recordkeeping, and additional trips for sign placement and maintenance. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1842)

<u>EPA Response</u>. It appears that this commenter has confused the costs of obtaining certification to use restricted use products with pesticide safety training under the WPS. Safety training is typically conducted on-site, often by the employer if he or she is a certified applicator, and under the revised set of topics, pesticide safety training will likely take 45 minutes to an hour.

<u>Comment</u>. EPA has underestimated the costs of the revisions because some states have higher labor costs, especially Hawaii. Average cost per farm does not reflect establishments with large numbers of workers. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2200, #2282, #2320)

<u>EPA Response</u>. EPA acknowledges that there is a great deal of variability across states and agricultural entities, but averages provide a powerful tool for calculating national-level impacts and for providing basic information about the impacts of policy options and decisions. EPA used variations in the number of workers across regions of the country to better understand the range of impacts to farms of different sizes. Although the average cost per farm may underestimate the cost to establishments with large numbers of workers, it also overestimates the impacts to establishments with few workers.

<u>Comment</u>. By averaging the number of employees so broadly EPA has significantly underestimated the total impact of compliance on growers of vegetable, fruit, and nuts, nurseries and greenhouses – those that employ the vast majority of farmworkers that engage in hand labor activities. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2200)

<u>EPA Response</u>. EPA disagrees. The analyses of both the proposed and final revisions include discussions of the impacts on individual establishments across a range of farm types and sizes, including different number of workers and handlers. This discussion is provided throughout Section 3.3 of the Economic Analysis of the final revisions; see, for example, Table 3.3-56 in Section 3.3.8. Also see Section 3.5, Small Business Impacts.

<u>Comment</u>. The US Census for Agriculture makes a distinction between hired farm labor and migrant labor. To get an accurate assessment of the impact on employers, contract labor must be included in the calculation. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2209, #2296)

<u>EPA Response</u>. EPA acknowledges that the Census of Agriculture does not account for contract labor. However, employment figures in the Census of Agriculture include employees who do not engage in hand labor activities or handle pesticides and count persons multiple times if employed at multiple establishments. As a result, the number of affected workers is likely overestimated. For the EA for the final rule, EPA estimates there to be almost two million workers, based on data from the Census, while USDA estimates that there are just over one million workers, including 200,000 workers employed through contract services, based on more refined data from farm labor reports (Ref. 24). As a result, national and regional level impacts are likely overestimated.

Comment. To try to better understand the details of the incremental cost increase claim, Bayer Crop Science and CropLife America examined the estimated burden of the ongoing WPS by looking up the most recently approved ICR, EPA No. 1759-06. The estimated annual burden to agricultural employers for the existing WPS is actually 1,827,493 hours at a cost of \$92,729,052. The expanded WPS ICR proposal calls for 8,316,993 hours and \$196,130,463, which appears to be a much higher dollar value than the incremental increase put forward in the economic analysis document. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1763, #2209)

EPA Response. The Economic Analysis is the better source to understand the estimated incremental cost of the rule. Comparing ICRs confounds different changes as explained in Chapter 7 of the analysis of the proposed rule and in Chapter 4 of the analysis of the final rule. First, the ICRs capture the 'paperwork' burden associated with the rule at different points in time. Thus, there will be differences in key parameters such as the wage rates and the number of affected entities (e.g., farms and workers). In contrast, the Economic Analysis is an assessment of the impacts of changes to the rule, i.e., with and without revisions to the WPS holding other parameters constant. Second, in developing the ICR to accompany the proposed (and final) rule revisions, EPA developed a more detailed accounting of the activities employers and employees and revised many estimates of the time needed to comply with the existing and new requirements. Finally, it should be noted that the ICR only captures the 'paperwork' burden associated with the rule as a whole. Impacts of a minimum age, for example, will not be captured through an evaluation of paperwork requirements.

<u>Comment</u>. Costs associated with the record keeping provisions need further explanation. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0153)

<u>EPA Response</u>. Details on the activities associated with the record keeping requirements have been provided in Appendix A of the analysis of the proposed revisions and in Appendix B of the analysis of the final revisions.

2. Training Costs

<u>Comment</u>. EPA has underestimated the time required for training. Videos used run 35 minutes for worker training and 50 minutes for handler training, respectively. Additional time beyond running the video is needed. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2320)

<u>EPA Response</u>. EPA acknowledges that training times may vary. However, using an average facilitates estimation of the national level impact and provides a concise measure of the impact per establishment.

<u>Comment</u>. This year we have spent 2092.37 hours training 4456 employees on the WPS/Pesticide function alone. If we use an average field wage of \$11.00 per hour, that is \$23,016.00 just on WPS/Pesticides. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1871)

<u>EPA Response</u>. EPA appreciates the information and notes that 2092 hours to train 4446 employees implies an average of 28 minutes of training per employee.

<u>Comment</u>. USDA suggested that more sensitivity analyses should be conducted around different training parameters such as the typical duration, the frequency at which workers are trained, and the frequency different types of trainers are used. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0153)

<u>EPA Response</u>. EPA conducted some sensitivity analyses for the proposed rule. Because the baseline costs and costs under the alternative, proposed, and final requirements are influenced by the same parameters, the incremental costs are often not substantially different. The number of affected entities and workers/handlers carries the largest influence on the estimates of the total cost.

<u>Comment</u>. The cost of developing the new material, either by the Agency or private entities, is not included in the analysis but should be considered. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0153, #2209)

<u>EPA Response</u>. EPA plans to develop revised materials for safety training and the safety information display. This is part of EPA's on-going work.

<u>Comment</u>. The proposed expanded content covers areas that are included in most food safety related training programs. The complexity and level of detail indicated in the proposed regulation would

take much more than just an additional 15 minutes as suggested in the rule. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2452)

<u>EPA Response</u>. EPA disagrees that the content is similar. The expanded content is primarily about informing workers how they can avoid inadvertently carrying pesticide residues home with them. EPA has pilot tested training using some of the material and has found that it can be covered in the suggested time frame.

<u>Comment</u>. The cost of providing training in different languages other than English should be included in the estimates. The average 1.5 training sessions expected annually at a large WPS farm does not appear to include sessions in different languages. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0153)

<u>EPA Response</u>. Establishments are not required to provide training in different languages, only in a manner that can be understood, which can include the use of imagery (posters or videos) as well as select translations. The estimated average of 1.5 training sessions per year under the final requirements is an average across all farms, considering different sizes of farms (according to the Small Business Administration definition, which is based on value of production and different numbers of workers). For example, a large farm (production value of at least \$750,000/year) that employs an average of 50 workers is anticipated to hold six to seven training sessions, on average, under the new requirements. This could include sessions in different languages, if the establishment found it convenient.

<u>Comment</u>. EPA did not consider the costs for Train-the-Trainer programs. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2209)

<u>EPA Response</u>. EPA did not estimate the cost of expanding Train-the-Trainer programs. The final rule retains certified applicators as qualified trainers and EPA does not anticipate that an expansion of Train-the-Trainer programs will be necessary.

<u>Comment</u>. The American Farm Bureau (AFB) raised several general concerns and applied them to the specific policy issue of Immediate Training (elimination of the grace period between beginning field work and receiving pesticide safety training). (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2200, #2206, #2439, #2442)

General Concerns

- 1. Underestimation of the number of farms
 - Census reports of hired labor do not include contract labor
 - Concern that EPA limited farms to those that derive their predominant source of revenue from sales of fruits/nuts, vegetables, nurseries, and greenhouses
 - Use of 2007 Census data
- 2. Underestimation of the number of workers
 - Census reports of hired labor do not include contract labor
- 3. Underestimation of wage
 - Use of 2007 data
 - Use of national level data
- 4. Farm structure
 - Use of average farm size (20 workers/large farm, 3.6 workers/small farm)
 - Assumption that all workers are present throughout the year (no seasonality of employment)

Specific Concerns with Immediate Training (example in Section 3.3.3 of Economic Analysis of Proposed Rule)

Under current requirements, workers must be trained every five years. EPA estimates that each worker spends 30 minutes in training at a wage rate of \$13.43 per hour including benefits. EPA estimates that currently, 48.9 percent of workers need to be trained each year given the assumptions that all new employees will take the training (16 percent of the workforce) and 40 percent of the returning workforce (84 percent of the workforce) will take full training each year EPA notes that small farms with fewer than ten workers are likely to hold 0.7 training sessions each year on average, small farms with more than ten workers hold an average of 2.2 training session per year, large farms with fewer than ten workers will hold 0.9 sessions per year, and large farms with more than ten workers hold 4.5 sessions per year. Despite these large differences, EPA's calculations are based on one full training session each year.

Under the proposed new requirements, workers must be trained every year. EPA estimates that each worker will now spend 45 minutes in training EPA estimates that in the first year of the new requirements 50.8 percent of workers need to be trained, and in each subsequent year 49.6 percent will need to be trained, again given the assumptions that all new employees will take the training (16 percent of the workforce) and 40 percent of the returning workforce (84 percent of the workforce) will take full training each year. EPA assumes that, on average, a WPS farm will need to conduct 1.5 full trainings each year on average, over all farms, since workers may be hired at different times during the year.

A. The amount of time a worker spends in training should also include travel time back and forth to the training facility in addition to the actual length of the training. A likely scenario is that workers will be called out of the field to complete the training, take some time to get seated and prepared for the session, complete the training, and then travel back to the field to continue work.

B. EPA should use updated, regional wage data.

 C. The seasonal nature of agricultural work and the fact that many workers are employed through labor contractors imply that the workers go through the WPS training several times. AFB expects that employers will train every worker, every year.

 D. The use of a simple average of one training per year is misleading. EPA Response.

1. EPA acknowledges that the Census of Agriculture does not account for contract labor under reports of hired labor and this could lead to an underestimation of the number of entities affected by the rule. However, the Census reports of hired labor include many employees who are not covered by the WPS because they are not engaged in hand labor activities or in handling pesticides for crop production. Moreover, EPA estimated total costs over a range of assumptions about the affected farms, nurseries, and greenhouses. EPA considered all farms regardless of the predominant source of revenue, even including farms who primary production is livestock. For the final rule, estimates were updated using data from the 2012 Census of Agriculture.

2. Again, EPA acknowledges that the Census of Agriculture does not account for contract labor under reports of hired labor, but it does include many employees who are not covered by the WPS. EPA estimates costs across a range of values for the number of workers. Our primary estimate is almost two million workers. This is in contrast to USDA's estimate of just over one million workers, including 200,000 workers engaged through labor contracts (ERS, 2014). EPA is confident we have not underestimated the number of workers in the cost estimation.

- 3. EPA has updated wages, using data from 2014 as reported by the Bureau of Labor Statistics to estimate the cost of the final revisions to the WPS. Using national level data is appropriate for estimating total national costs.
- 4. Relying on the average number of workers per farm and assuming they are present the entire year results in an overestimation of costs, both in total and per farm. EPA uses an average across farms accounting for all employees on the farm regardless of length of service. It is not the average workforce per farm across time. We assume these employees are all workers and are present the full season. However, many workers are present on a farm for a short period of time around harvest and certain requirements, like notification and posting of pesticide applications, are only required for those pesticide applications relevant for that period, not for applications when workers are not present. Thus, EPA is overestimating the cost of complying with such requirements by assuming that workers are present the entire season. Note that there are also exceptions for applications occurring on fields far removed from workers' location.
 - A. EPA sees no reason to include travel time as part of the scenario for pesticide safety training. Such a scenario would be highly inefficient; employers are highly likely to provide training prior to the work day, not interrupting it. This is especially true under the final rule, which eliminates the "grace period" and requires each worker to be provided with safety training prior to entering a previously treated field. Finally, the requirement to provide safety training is not new. If it were a normal practice for an employer to halt work for a training, this would be true in the baseline as well as under the new provision. Thus, the incremental difference in time is still only the additional time to cover a few additional training topic.
 - B. EPA has updated wages, but is not using regional wage data. EPA acknowledges that there is a great deal of variability across states and across agricultural entities, but averages provide a powerful tool to understand the impacts of policy options. Although an average wage may underestimate costs in some states, it will overestimate costs in others.
 - C. EPA agrees that, because workers may be engaged by multiple employers, workers may attend multiple WPS trainings each year. Since the Census surveys farms about the number of employees, it will count such workers multiple times. Because EPA's approach includes all employees enumerated in the Census, we essentially account for multiple trainings. Training records and documents may reduce repeated trainings, especially for workers engaged through labor contractors. Finally, if employers are already training every worker every year, the impact of requiring annual training will be negligible.
 - D. EPA reiterates that use of averages simplifies many of the calculations, particularly for national level costs. However, in estimating the impacts on farms of different sizes and types, EPA considers that many farms will provide more than a single session while, currently, some farms may only be providing safety training every few years.

Comment. The Hawaiian Commercial and Sugar Company believes that the amount of time needed to cover the additional topics proposed to be added has been underestimated, and that both the additional time and additional expense of meeting the new training requirements will be higher than EPA has estimated. It does not appear that EPA's estimate of \$3 in additional annual training costs per agricultural establishment is remotely reasonable, particularly for establishments with large numbers of agricultural workers who must attend the training. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2320)

<u>EPA Response</u>. EPA is unclear as to the referenced estimate of \$3 in additional annual training cost per establishment. EPA estimated that annual training would cost an additional \$22 per

establishment, on average, and that expanding the training content would cost an additional \$11 per establishment per year, on average (Section 3.3.3 of the EA for the proposed revisions to the WPS). Based on data from the 2007 Census of Agriculture, the average establishment produced about \$470,000 in annual value of production and employed six workers and handlers. All proposed revisions to the training requirements were estimated to cost about \$240 for the average large farm, which produced about \$2.4 million in annual value of production and employed 20 workers and handlers (Section 5.2.1 of the EA for the proposed revisions to the WPS). All final revisions to the training requirements are estimated to cost about \$210 for the average large farm, which, based on data from the 2012 Census, produces approximately \$2.4 million in annual value of production and employs 18 workers and handlers (Section 3.3.1 of the EA for the final revisions to the WPS).

<u>Comment</u>. EPA asserts that tracking, maintaining, producing, and distributing training records both for internal and employee use will cost establishments \$4.00 a year. We find this number to be a gross underestimate and plead with EPA to simplify the requirements for record keeping. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1879, #2222, #2377)

EPA Response. EPA appreciates the comment, but without additional information is unable to determine how the estimation should be modified. EPA notes that the cited cost of \$4 to \$5 per year is for worker training only and did not account for the increase in the number of training sessions arising from the annual training requirement. Considering the annual training requirement, EPA estimated recordkeeping costs associated with worker safety training to be \$5 to \$11 per year, on average. The final rule modifies the record keeping requirements somewhat, reducing some of the information that must be kept and specifying that agricultural employers only have to provide a copy of the record to a worker or handler if he/she requests a copy. Details of EPA's estimation, including the time required for record-keeping are found in Appendix B of the Economic Analysis for the final rule. Considering the changes to the rule and new wage information, EPA is estimating that record-keeping costs associated with worker and handler training may range from \$5.60 to \$14.20 per year.

<u>Comment</u>. The estimated costs for creating worker and handler training records and retaining them for two or five years is not well explained in the EA. Costs of producing and retaining the record should be discussed. It is unclear how costs were derived. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0153)

<u>EPA Response</u>. Details on the activities associated with the record keeping requirements have been provided in Appendix A of the analysis of the proposed revisions and in Appendix B of the analysis of the final revisions.

3. Hazard Communication Costs

<u>Comment</u>. The National Council of Agricultural Employers asked members about EPA's estimated time to comply with the proposed hazard communication requirements and provide the Agency with the replies, three of which are relevant to the estimation of costs. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1871)

- 1. Agency estimates employers will take 12 minutes to gather information and will do it an average of 20 times annually. Do employers think this is reasonable?
 - Our Safety Supervisor spent 2 days (16 hours or 960 minutes) compiling all MSDS/SDS and labels for all locations.
- 2. Agency assumes filing of record, label and SDS will take 1 minute per application (20 minutes per year total. Do employers think this is reasonable?

6669 Putting a MDSD/SDS or label in a book or binder may take 1 min each if they are in a stack 6670 waiting for you and this is simply all that you are doing. That would never be a realistic 6671 assumption.

3. Agency assumes a worker, handler or representative for a worker or handler makes a request for information on 25% of the applications and it requires 6 minutes of the employer's time to provide the information. Is 6 minutes enough to allow for discussion? Should it be recorded a request was made and by whom and why?

Again this would assume you are doing nothing else but sitting and waiting for a request and you have the information in front of you. I think the request should be recorded and kept on file in case something comes from that request. That way you could prove compliance with the requirement.

EPA Response. EPA appreciates the effort taken by NCAE to solicit information.

- 1. The reported time appears to be substantially more than estimated by EPA (4 hours per year, on average). However, without knowing the number of applications involved, EPA does not have sufficient information to revise its estimates. In fact, it would seem that this situation involves an employer much larger than average. Most farms do not have a dedicated safety supervisor. Further, it appears that the farm is already collecting SDS so no additional effort would be required for the farm to gather the information to provide to workers.
- 2. As EPA has detailed in the cost estimate (see Appendix B of the Economic Analysis of the final rule, Table B.2.b-1), filing the documentation is only one final step. Gathering and recording the information is accounted for separately. The comment suggests that EPA's estimate of filing the documents is reasonable.
- 3. EPA appreciates that the comment suggests that the time to respond to an employee's request for application information is underestimated in EPA's analysis. For the final rule, EPA maintains the estimate of 6 minutes to honor a request from a worker on site for the hazard information since it is likely that the request can be easily clarified and, in fact, the information should be readily available and easily provided to the employee. EPA revised the time needed to respond to a request from a former worker or through a designated representative to 20 minutes per request since it may be more difficult to identify the appropriate information for such a request and providing the information to the employee/representative is more complicated.

4. Notification Costs

<u>Comment</u>. WPS warning signs commonly used in horticultural growing operations are reported to cost around \$6.00 each. Large operations may maintain 1000 or more signs. How did the Agency arrive at the conclusion that the cost to implement the warning sign change would be \$0.25 per establishment? A requirement to change warning signs constitutes significant cost burden. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2287)

<u>EPA Response</u>. EPA proposed a revision to the wording on the warning signs, but also proposed a transition period so that signs with the former wording could be used until replacement due to wear and tear, implying little cost to the grower. In the final rule, however, EPA is retaining current sign format, so no new signs are required.

<u>Comment</u>. The time required to travel to sites should be added to the cost of posting pesticide safety posters. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1871)

<u>EPA Response</u>. Since decontamination supplies must be provided at these sites, posting the safety poster could reasonably be combined with delivering decontamination supplies, so no additional travel time is needed to post a safety poster.

<u>Comment</u>. Required information to be included on safety posters will mean posters must be replaced annually. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1871)

<u>EPA Response</u>. The required information is contact information for a nearby medical facility and for the state lead agency. This information is unlikely to change frequently. Further, updating contact information may not necessitate replacement of the entire displays. The information can be written, erased, and rewritten on some signs and updated information could taped over the old information. *5. PPE Costs*

Comment. Current regulations require the handler employer to confirm that a respirator is fit properly. The new regulations require fit test, training and medical evaluation conforming to OSHA requirements and recordkeeping. The baseline estimate for obtaining a fit test is not well described and it is unclear what assumptions were made for current practice. The incremental difference between the baseline and new requirements doubles the baseline cost but may understate the difference as it is unclear what current practice entails. Sensitivity analysis about the travel and wait time for medical examinations and cost of follow-up medical examinations could provide a range of likely values for the proposed alternative. The cost of travel, as well as time spent traveling should be included in the cost. Presenting a range, rather than a point estimate, incorporates some acknowledgement of uncertainty in these calculations. If the baseline is actually 'lower' than EPA is assuming, the benefits and costs of the new requirements will both be higher. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0153)

EPA Response. EPA assumed very minimal procedures in the baseline for most situations. Appendix A of the analysis of the proposed revisions described these as the employer and handler checking the fit and going over the use instructions for a total of 12 minutes (0.2 hours) each year. If anything, this probably understates the care employers take with the handlers in their employ. EPA also assumed that less than 1,000 handlers followed OSHA-like procedures in the baseline because they are required to do so by the labels of soil fumigant products. Cost of travel was and is included in the estimation of costs under the proposed and final rule, for both obtaining a follow-up medical examination, if necessary, and for the fit test, if conducted off-site. See Appendix B of the EA for the final rule, Table B.6.a-1 and B.6.a-2.

<u>Comment</u>. The following are the costs for a fit test and medical evaluation: For a qualitative (smoke) fit test the cost is \$12; For a quantitative computer fit test the cost is \$24; Charges in the amount of \$30.00 is paid to obtain the medical evaluation paperwork. The person obtaining the fit test and evaluation must then be signed off by a physician that they are physically able to use a respirator. Routine visits to a medical provider start at \$100 + per visit. Additional costs include employee wages and benefits, plus travel costs to a certifying physician. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1843)

EPA Response. EPA appreciates the information and has revised the scenario used to estimate the cost for the respirator medical evaluation, fit testing and training. We found similarly priced evaluation screens but note that it would generally not be necessary to visit a physician or clinic to complete the evaluation. EPA also assumes that most agricultural establishments will send handlers to a central location rather than purchase a test kit although fees may be somewhat higher than this comment reports, given other comments received. EPA includes the cost of the employee's time, including travel, for the fit test as well as time for the employer to oversee the process. EPA estimates the total cost of complying with the respirator fit test requirements to be about \$180 per handler, on average, who is tested. See Section 3.3.6 of the Economic Analysis for the final rule, including Appendix B.6, Table B.6.a-1, for details.

Because there were many concerns raised for the respirator requirements, EPA plans to develop detailed information describing the specifics for employers and their handlers.

<u>Comment</u>. Commenters believe the requirement for medical evaluation will be a significant cost on handler employers and difficult to carry out. EPA's cost estimate of \$54 per agricultural establishment is unrealistically low. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1842, #1848, #1871, #2385)

EPA Response. As indicated by the previous comment and explained in Section 3.3.6 of the Economic Analysis for the final rule and Appendix B.6, the medical evaluation for a handler to safely wear a respirator is not complicated. The evaluation is typically a questionnaire that can be completed, submitted, and reviewed on-line. A visit to a physician is not necessary, unless the screening evaluation indicates a more thorough physical examination is needed to ensure the handler can safely wear a respirator. EPA estimates the cost of the respirator-related requirements to be about \$150 for a handler, on average, but could be around \$270 if a more thorough medical examination is warranted. Not every establishment will use products requiring a respirator every year, however, so the average cost across all agricultural establishments is substantially lower.

<u>Comment</u>. The OSHA standard requires the use of respirators certified by the National Institute for Occupational Safety and Health (NIOSH). If EPA adopts the OSHA requirements then it needs to document the cost of purchasing certified respirators (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2385).

<u>EPA Response</u>. The cost of respirators is not relevant to the requirement of proper fit established in the WPS. Specific respirator requirements are already mandated on product-specific pesticide labeling.

<u>Comment</u>. Requiring noncertified crop advisors to wear PPE when entering fields under a REI will weaken the producer's ability to implement prevention-based IPM programs, and pesticide use, including more toxic pesticides, will rise as a result. Independent crop consulting firms will have to reduce reliance on uncertified employees, doubling labor costs and increasing fees. Growers will reduce scouting and instead rely on more pesticides. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2257, #2307)

EPA Response. Comments appear to reflect a misunderstanding of the revision. PPE are required by the pesticide label for individuals entering a field under a Restricted Entry Interval (REI) immediately following a pesticide application. The existing WPS requires certified crop advisors to have PPE available for themselves and non-certified crop advisors in their employ or under their supervision. However, the WPS exempts certified crop advisors and non-certified crop advisors in their employ or under their supervision from wearing it if they judge the risks to be acceptable. The revision simply eliminates the exemption for a non-certified crop advisor to forgo wearing PPE in a field under a REI, based on his/her employer's recommendation. While the PPE specified in the existing WPS is the label-specified PPE for handlers, the revised rule would relax this requirement to allow crop advisors and those in their employ or under their supervision to choose a reduced set of PPE. That is, the only impact of the provision is that the non-certified crop advisor may have to put on available PPE (essentially coveralls and gloves) if they enter a field under a REI.

Comment. The National Alliance of Independent Crop Consultants expressed concern that certified crop advisors or the establishments on which they are employed would need to furnish additional PPE for employees if they are required to change or throw away PPE each day as disposable PPE is not as durable as normal work wear that can be carefully washed and reused. "For example Tyvek suits, which are the most common type of disposable PPE clothing, are extremely susceptible to rips and

tears under normal levels of activity, especially the inseam. Due to the high temperatures and humidity inside a Tyvek suit, employees often wear shorts under these suits, and a torn inseam then creates greater potential for exposure than had they been wearing long pants, the minimal PPE recommended by the NAICC's position statement on Employees of Certified Agricultural Professionals." (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2307)

<u>EPA Response</u>. In the final rule, EPA provides three PPE options for noncertified crop advisors and employees entering areas during an REI that should minimize disruption in IPM practices. They may wear the handler PPE from the labeling, the PPE for early entry, or they may wear coveralls, shoes and socks, chemical resistant-gloves, and eye protection (if the label requires eye protection). It is worth noting that the coveralls can be made of cloth and Tyvek suits are not required.

<u>Comment</u>. Costs of retrofitting existing closed loading systems to meet the requirements of California's Director's memo are underestimated. CropLife America estimates that converting an existing system to meet the proposed standard would cost \$25,000 to \$100,000. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2209)

EPA Response. Based on significant comments related to the closed system criteria in the proposal, EPA has revised the final rule to provide a closed system performance standard. CropLife did not provide a basis for the estimate of retrofitting costs. However, according to a study by Giles and Billings (2013), a simple closed system meeting the standard in the final rule would cost about \$330. EPA estimates that retrofitting existing systems would likely mean purchasing an appropriate adapter to connect the pesticide container to a mixing tank or to the application equipment at a cost of about \$150. See Section 3.3.6 of the Economic Analysis for the final rule.

6. Cholinesterase Monitoring

<u>Comment</u>. The Agency presented a simple cost analysis based on data collected in Washington in 2009. In comparison to Washington's total agricultural production value, the costs associated with the state's cholinesterase inhibition monitoring program are exceedingly small. More importantly, this analysis does not include an estimation of the medical expenses that were saved, the lost wages prevented, and the pesticide-related illnesses avoided as a result of early detection and intervention. Washington State's example shows that ChE monitoring program is not only cost effective but also enhances the health and safety of workers who directly handle pesticide products. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2393)

EPA Response. The comment's description of the cost analysis omits the costs borne by the employer and handler in terms of the time required for the program. EPA acknowledges that the analysis did not attempt to quantify the benefits attributable to a monitoring program alone, primarily because of the difficulty in isolating the effect of one particular program in terms of preventing pesticide-related illnesses. As discussed in the Economic Analysis of the Proposed Revisions to the WPS, Section 4.5.3, however, the benefits in terms of preventing pesticide-related illnesses may be small. Instead of requiring medical monitoring, EPA is instituting better practices, such as improved training in the use of PPE, which the Washington state program identified. These improved practices will be required for all handlers, not just those handling pesticides that may inhibit cholinesterase.

7. Employment Impact Analysis

<u>Comment</u>. Current WPS regulations have had the unintended consequence of causing some famers to avoid hiring workers and complying with the related WPS training and recordkeeping requirements. This may be having a negative economic impact on the growth and competitiveness of small lowa farms. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2206)

<u>EPA Response</u>. EPA has seen no studies suggesting that farmers forego hiring workers or handlers due to the cost of complying with the WPS. EPA estimates that the incremental cost of the revisions will add about \$5.00 per year to the cost of a worker, which is unlikely to have sizeable consequences on farmers' hiring decisions. See Section 3.3.4 of the Economic Analysis for the final rule. *8. Small Business Impact Analysis*

<u>Comment</u>. Many small businesses believe that EPA's anticipated impact of less than 0.1 percent is understated and recommend that EPA perform an additional sensitivity analysis related to small commercial entities before certifying the proposed action will not have a significant adverse economic impact on them. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1843, #1870, #1871)

<u>EPA Response</u>. EPA has performed a sensitivity analysis around the estimated costs to small businesses. The SBA defines a small agricultural establishment as producing less than \$750,000 in agricultural output. EPA examined the impact of the proposed and final rule changes on establishments throughout the size distribution, including on establishments producing less than \$10,000 in agricultural output.

Comment. EPA finds that estimated costs would equal to almost two percent of smaller small entities' revenues independent of other costs and economic circumstances that might be associated with this rulemaking or the specific industry. Based on this average, which is greater than one percent, EPA's factual basis contained in the economic analysis does not provide adequate support for EPA's certification that the rule will not have a significant economic impact on a substantial number of small entities. EPA should, therefore provide a full initial regulatory flexibility analysis, including regulatory alternatives to reduce the adverse economic effects on the smaller small entities. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1848)

EPA Response. EPA examined the estimated impacts of the revisions to the WPS in detail and the results are presented in both the Economic Analysis of the Proposed Revisions and of the Final Revisions. See Section 3.5 of the EA for the Final Revisions. EPA estimates that the smallest of farms, given 3.7 workers on average and relatively low pesticide use, may face incremental costs of about \$86 per year, but more likely costs of \$30 to \$50 per year given the seasonality of the labor they employ. Impacts are compared to the value of agricultural production, but this measure understates the establishment's total income. According to the 2012 Census of Agriculture, 92 percent of establishments producing less than \$10,000 in agricultural production make less than 25 percent of their income from farming. Farm-related income, which includes activities like agricultural services, land rent, and agrotourism, account for 35 percent more income for these establishments than does agricultural production. Further, EPA estimates that impacts of this magnitude or greater will be felt by those small-small farms that primarily produce fruits, nuts, and vegetables and small-small nurseries and greenhouses. These entities number about 12,000, comprising only six percent of all WPS farms.

<u>Comment</u>. Small businesses are concerned with the use of national averages across all farm sizes. This is approach does not account for the seasonal nature of the workforce prevalent in most small entities. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1848)

<u>EPA Response</u>. The Census of Agriculture reports the total number of persons employed by an establishment, regardless of the length of employment. Although the agricultural workforce is highly seasonal, EPA assumed that all workers on an establishment were present for the majority of the time. This assumption likely results in an overestimate of the cost of compliance, particularly compliance with the hazard communication and notification requirements because it assumes that all workers are informed of all pesticide applications made on the establishment.

<u>Comment</u>. EPA does not provide any cost adjustment for small agricultural entities nor provided any alternative methods of compliance. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2209)

<u>EPA Response</u>. The Regulatory Flexibility Act (RFA) requires agencies to assess the impacts of regulations on small entities and to consider ways in which the burden can be reduced. Neither the RFA nor the Paperwork Reduction Act requires agencies to provide alternative methods of compliance. Pursuant to the RFA, EPA assessed the impacts to small agricultural entities and considered several recommendations made by a panel of small business representatives in developing the proposal and final rule. Ultimately, EPA's analysis indicates that there will not be a significant impact to a substantial number of small businesses.

9. State Costs

 <u>Comment</u>. EPA's economic analysis does not fully and accurately account for the costs to the FIFRA-state lead agencies. These costs will be significant, especially during the first several years of implementation. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1763, #1870, #1871, #1874, #2206, #2208, #2209, #2258, #2282, #2293, #2313, #2432)

<u>EPA Response</u>. The Economic Analysis of the final rule includes a discussion of the impacts on states.

<u>Comment</u>. The Economic Analysis did not account for the increased cost of training sufficient trainers to comply with the proposed requirement that worker safety training be conducted by trainers of certified applicators or by persons who have completed a Train-the-Trainer course. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1870, #2293)

<u>EPA Response</u>. EPA did not estimate the cost of expanding Train-the-Trainer programs. The final rule retains certified applicators as qualified trainers and EPA does not anticipate that an expansion of Train-the-Trainer programs will be necessary.

10. ICR

<u>Comment</u>. CropLife America and Bayer CropSciences raised several concerns over the burden and cost estimates of the proposed ICR. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1763, #2209)

- EPA used loaded wages (monetary compensation plus non-monetary benefits such as paid leave and insurance) rather than fully loaded wages (monetary and non-monetary compensation plus overhead for equipment and infrastructure).
- EPA underestimated the number of greenhouses.
- EPA should have used a minimum of five minutes for every record-keeping activity.
 - set-up costs to establish a record-keeping system if one has not already been established
 - costs to develop internal record forms
 - o printing costs for paper records
 - o computer software/system costs for electronic records
 - storage costs
 - o disposal costs of records with sensitive information
 - maintenance costs for records beyond the two-year minimum for longer-term employees
- Added costs for Train-the-Trainer programs.

6937 <u>EPA Response</u>.

EPA agrees that it is appropriate to use the fully loaded wage rates for employers and for
pesticide handlers, since these actors are using equipment and infrastructure that depreciates
and must be replaced. However, EPA thinks it appropriate to use loaded wage rates for
workers, since these employees typically are not using such equipment. Further, agricultural
workers often do not receive non-monetary benefits so any use of infrastructure is captured
within the loading factor.

- EPA disagrees that the number of greenhouses is underestimated. Publicly available data from the Census of Agriculture do not permit the identification of the number of farms that both use pesticides and hire labor nor does it report greenhouses separately from nurseries and floriculture production, which are all included under NAICS code 1114. For ICR, both for the proposed and final rule, EPA estimated the number of farms, including greenhouses, that use pesticides and/or hire labor based on publicly available data from the 2012 Census of Agriculture and the information from the special tabulation of data from the 2007 Census. Please see Appendix A of the Economic Analysis of the Agricultural Worker Protection Standard revisions for details of the estimation procedure. EPA acknowledges that there are many more greenhouses in operation than are reported under NAICS code 11141 because U.S. farms typically produce a diverse array of crops and NAICS codes reflect only the primary source of revenue for an entity. However, since those greenhouses are reported as part of other entities listed under other NAICS codes, EPA is confident that this ICR accounts for the full burden of compliance with the WPS.
- EPA does not think a minimum of five minutes for each recordkeeping activity is warranted. EPA has frequently defined very limited activities to separate the gathering of information, which may vary by the type of information, from the filing and storing of the information, which is likely similar across types of information and takes very little time once the information is gathered. EPA also does not think it necessary to include set-up costs, since agricultural establishments hiring labor will already have some recordkeeping system in place. The final rule does not require collection of sensitive information and since the rule does not require maintenance of records beyond two years the ICR should not include such costs.
- EPA did not include costs for train-the trainer programs because most costs are covered by fees paid by those participating in the course. However, EPA acknowledges the concerns raised by stakeholders about the availability of trainers as well as the skills necessary to provide pesticide safety training for agricultural workers. In the final rule, EPA is retaining the provision that worker safety training may be conducted by certified applicators, so the cost of training additional trainers is no longer relevant.

<u>Comment.</u> EPA's analysis must meet data quality guidelines of objectivity, utility, and integrity. While EPA's FIFRA pesticide registration are based on individual and cumulative risk assessment, the WPS analysis is not based on any risk assessments at all. OMB should not approve the WPS ICR because the ICR does not meet IQA guidelines and practical utility. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0480)

<u>EPA Response</u>. EPA's analysis is based on the best and most appropriate data available and meets the Agency's as well as OMB's quality guidelines. The WPS analysis is not based on chemical-specific risk assessments like pesticide registration decisions because it is not a chemical-specific rule.

<u>Comment</u>. The draft ICR does not account for the costs to the FIFRA-state lead agencies. These costs will be significant, especially during the first several years of implementation. (Comments in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1763, #2209)

<u>EPA Response</u>. Neither the current WPS ICR nor the draft ICR includes a measure of the paperwork burden for state lead agencies charged with enforcement of the WPS. The ICR for the WPS has always focused on the burden to agricultural establishments, commercial pesticide handling establishments, workers, and handlers. In general, State reporting requirements are addressed in "EPA's General Regulation for Assistance Programs ICR" (OMB number 2030-0020; EPA No. 0938.18).

<u>Comment</u>. Rule Familiarization is not a one-time review. Material must be reviewed throughout the year. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1871)

<u>EPA Response</u>. EPA agrees that an employer may review WPS material multiple times in the year. The ICR estimates an annual average for a three-year period (the time period covered by the ICR) that agricultural employers, as well as the operators of farms that do not hire labor, spend to familiarize themselves with the rule. The estimate is for the average time annually, estimated at 30 minutes, but does not specify the frequency of the rule reviews. The comment does not provide an estimate of the time spent per review of the material or the number of reviews to inform whether the current estimate is low or high. If such information is provided, EPA can consider this information to incorporate it into future ICRs.

11. Other

Comment. Farmers' ability to comply with immense quantities of regulations also differs from other businesses since farmers do not set the price on their commodities and they sell their commodities at a price determined by the market regardless of a farmer's input costs. In some years, when crop prices or crop yields or both are low, farmers have limited funds to purchase large amounts of additional equipment or to pay an additional salary for someone to do additional EPA recordkeeping. Commodities prices such as corn and sugar are significantly below average which means farmers will have far fewer dollars to pay for additional EPA compliance costs. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2443)

<u>EPA Response</u>. EPA recognizes that farmers face risks associated with price variability and production variability. However, the revisions to the WPS do not entail investments in additional equipment, except for, perhaps, an additional fitting to complete a closed pesticide delivery system, and the recordkeeping requirements are unlikely to necessitate a dedicated employee. In the final rule, EPA has eliminated some of the proposed recordkeeping requirements in order to focus those requirements on areas of importance. The required safety training records and application records are not wholly new; farmers already must keep employment records and often will maintain pesticide application records for reasons such as resistance management.

<u>Comment</u>. The significant added cost burden imposed by these revisions could be reduced by focusing on the gaps in the implementation of the current WPS, rather than by adding layers of bureaucracy and prescription. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2311)

<u>EPA Response</u>. EPA appreciates the comment, but without additional information is unable to address which gaps in the implementation of the existing WPS requirements the commenter identifies as significant problems.

<u>Comment</u>. The proposed changes to the WPS fail to adequately acknowledge the adverse economic impact on small nursery, greenhouse, Christmas tree, and floriculture operations, which were badly impacted by the economic downturn and the "great recession." Many growers have gone out of business; the recently-release Census of Agriculture suggests a nearly 25 percent decline in production

of woody nursery crops. Many growers who survived have lost equity and are still vulnerable. In this environment, increased regulatory compliance costs are destabilizing and often untenable. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2287)

<u>EPA Response</u>. EPA considered the impacts to all small entities, including nurseries and greenhouses. See Section 3.5 of the Economic Analysis of the final rule.

<u>Comment</u>. An academic organization recommends that the WPS should protect the health of vulnerable populations without regard to cost-benefit analysis, as is the case with health standards set under the Occupational Safety and Health Act (OSH Act) to protect workers from toxic substances and harmful physical agents, and dietary pesticide residue tolerances set under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#1384)

EPA Response. It is reasonable and appropriate to pay close attention to the anticipated costs and benefits of FIFRA regulation, and EPA does so in accordance with Executive Order 12866 and Executive Order 13563, among other applicable requirements. Unlike the certain regulatory standards of the OSH Act and FFDCA section 408, the FIFRA "unreasonable adverse effects" standard expressly requires that EPA take into account the economic, social, and environmental costs and benefits of the use of any pesticide. See FIFRA section 2(bb).

<u>Comment</u>. EPA should perform a retrospective analysis of the effects of the rule, including an analysis of the costs. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0444)

EPA Response. EPA will consider such an analysis at the appropriate time.

<u>Comment</u>. EPA has promulgated extensive regulations establishing other data requirements for the regulation of pesticides under FIFRA. Subpart K of these regulations govern "Human exposure," including "Applicator exposure" and "post-application exposure." Consequently, these EPA data requirement regulations apply to the WPS. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0480)

<u>EPA Response</u>. EPA's data requirements at 40 CFR part 158, subpart K, apply to pesticide registrants and specify the exposure data required to support a pesticide registration. Fulfillment of the data requirements enable EPA to conduct chemical-specific risk assessments to inform chemical-specific pesticide registration decisions. These requirements do not limit the Agency's authority to consider other reliable information that may be pertinent to a pesticide registration, or to the WPS.

<u>Comment</u>. While we appreciate the effort that went into the analysis, we suggest that the economic analysis section be subject to outside peer review to determine if the assumptions and uncertainties used by the agency adequately represent the real world and the current state-of-the-art. (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#2310)

<u>EPA Response</u>. Such a review is not a part of the regulatory review process. The analysis is subject to the OMB-led inter-agency review and review by the public.

<u>Comment</u>. One individual asked (Comment in regulations.gov, docket EPA-HQ-OPP-2011-0184; ID#0136)

- 1. What is the cost/benefit of implementing these new changes?
- 2. Currently, what is the number and severity of any pesticide injuries for each of the last three years?
- 3. In comparison to other work place injuries, where does the pesticide injuries stand?
- 4. What will be the economic impact of these new regulations if implemented? EPA Response.

- 1. The cost/benefit ratio is not defined, given the inability to estimate a monetary value for many of the benefits anticipated.
- 2. EPA provided the results of an analysis of incidents in Section 6.5 of the EA for the proposed ruleand updated the analysis for the final rule, presenting the results in Section 4.5.
 - 3. EPA did not compare other kinds of work place illness or injury to the incidence of pesticide. EPA's mandate under FIFRA is to protect human health, including the health of workers and handlers, and the environment from unreasonable adverse effects of pesticide exposure.
 - 4. EPA estimates the cost of compliance with the revised WPS to be about \$60 to \$67 million per year. EPA further estimates that the revisions will result in fewer occupational incidents involving pesticides and will reduce day-to-day pesticide exposure to workers and handlers as well as reducing the amount of pesticide residues inadvertently carried home by workers and handlers.
- 7082 Comments in Unit XX.A.

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- 7083 ID#0136. Anonymous Public Comment
- 7084 ID#0153. US Dept. of Agriculture
- 7085 ID#0205. Idaho Farm Bureau Federation
- 7086 ID#0444. George Washington University Regulatory Studies Center
- 7087 ID#0480. Center for Regulatory Effectiveness
- 7088 ID#1384. Center for Governmental Responsibility, Levin College of Law, University of Florida
- 7089 ID#1642. Texas Farm Bureau
- 7090 ID#1722. Elliot Gordon
- 7091 ID#1763. Bayer CropScience
- 7092 ID#1842. National Cotton Council
- 7093 ID#1843. Wyoming Dept. of Agriculture
- 7094 ID#1844. American College of Occupational and Environmental Medicine
- 7095 ID#1848. U.S. Small Business Administration, Office of Advocacy
- 7096 ID#1870. National Association of State Depts. of Agriculture
- 7097 ID#1871. National Council of Agricultural Employers
- 7098 ID#1874. Maine Dept. of Agriculture, Conservation, and Forestry, Board of Pesticides Control
- 7099 ID#1879. Wilbur-Ellis Company
- 7100 ID#2155. Minnesota Nursery and Landscaping Association
- 7101 ID#2238. Massachusetts Nursery and Landscaping Association
- 7102 ID#2199. USA Rice Federation
- 7103 ID#2200. American Farm Bureau Federation
- 7104 ID#2206. Iowa Farm Bureau Federation
- 7105 ID#2207. North Carolina Farm Bureau
- 7106 ID#2208. Pesticide Policy Coalition
- 7107 ID#2209. CropLife America
- 7108 ID#2222. North Carolina Dept. of Agriculture and Consumer Services
- 7109 ID#2225. Florida Nursery, Growers, and Landscape Association
- 7110 ID#2239. National Potato Council
- 7111 ID#2242. Utah Dept. of Agriculture and Food
- 7112 ID#2252. Ohio Farm Bureau
- 7113 ID#2257. Glades Crop Care, Inc.
- 7114 ID#2258. Georgia Dept. of Agriculture

7115 ID#2269. Western Growers 7116 ID#2282. Hawaii Farm Bureau 7117 ID#2286. Wyoming Ag-Business Association, Wyoming Crop Improvement Association, Wyoming Wheat 7118 7119 ID#2287. AmericanHort, Society of American Florists, National Christmas Tree Association, and 7120 California Cut Flower Commission 7121 ID#2293. State of Pennsylvania Dept. of Agriculture 7122 ID#2294. Pennsylvania Farm Bureau 7123 ID#2296. Georgia Farm Bureau 7124 ID#2303. Washington Friends of Farms & Forests 7125 ID#2304. Plains Cotton Growers, Inc. 7126 ID#2307. National Alliance of Independent Crop Consultants 7127 ID#2310. Northwest Horticultural Council 7128 ID#2311. South Dakota Agri-Business Association 7129 ID#2313. New Mexico Dept. of Agriculture 7130 ID#2319. Oregon Association of Nurseries 7131 ID#2320. Hawaiian Commercial and Sugar Company 7132 ID#2376. Kansas Dept of Agriculture 7133 ID#2377. African American Farmers of California, California Citrus Mutual, California Cotton Ginners 7134 Association, California Cotton Growers Association, California Fresh Fruit Association, Nisei 7135 Farmers League, Western Agricultural Processors Association 7136 ID#2385. Agricultural Retailers Association 7137 ID#2393. California Environmental Protection Agency 7138 ID#2432. Texas Dept. of Agriculture 7139 ID#2439. Michigan Farm Bureau 7140 ID#2442. MBG Marketing; Michigan Agricultural Cooperative Marketing Association; Michigan Apple 7141 Committee; Michigan Asparagus Growers, Inc.; Michigan Cherry Committee; Michigan Farm 7142 Bureau; Potato Growers of Michigan, Inc. 7143 ID#2443. Louisiana Farm Bureau Federation, Inc. 7144 ID#2452. Minor Crop Farmer Alliance 7145 ID#2491. National Agricultural Aviation Association 7146 ID#2492. New York Farm Bureau 7147 B. Benefits 7148 Comment. Several commenters dispute EPA's findings that there will be benefits from the 7149 changes to the WPS. These comments took several forms. Several commenters objected that EPA was 7150 unable to quantify benefits for specific proposals that are part of the changes to the WPS (1805, 1430, 7151 1012, 4529, 4543, 4531, 4533, 1369, 853, 697, 1809, 1436, 1809, 1436, 853, 4548, 4546). 7152 EPA Response. There are many changes to the WPS, and the changes work together to increase 7153 safety. For example the better communication of hazards works together with better training to ensure 7154 that farmworkers and handlers know better how to protect themselves and their families. The changes 7155 also work together with pesticide labels to ensure that pesticides can be used safely. For these reasons, 7156 the benefits of individual proposals could not be estimated. Because of the nature of pesticide 7157 exposure, the possible latency of effects, and the underreporting of pesticide incidents, it is difficult to

find precise estimates of the benefits of the WPS changes. The available evidence, however, is

convincing to EPA that the rule changes will result in benefits sufficient to justify the costs.

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<u>Comment.</u> Commenters also objected to the discussion of chronic disease reduction as a potential benefit of the rule, doubting that the WPS changes will result in reduced chronic illness (4461, 4442); objected to EPA estimating the value of reduced cancers, when the association between illness and exposure is speculative (576); and that the epidemiology literature cited only describes associations between pesticide exposure and illness, rather than causal relationships (4544, 1107, 4540). Some commenters objected that the epidemiology studies cited were old, and many were based on exposure that happened prior to the registration of new, safer pesticides (1369, 348).

EPA Response. EPA acknowledges that the pesticides registered for use are generally safer than in the past, and the Office of Pesticide Programs continually strives to strike an appropriate balance between pesticide effectiveness and safety. Despite continual efforts to improve safety, risks to farmworkers, handlers and their families remain. Studies of pesticide risks, such as epidemiology studies, such as the Agricultural Health Study (AHS) are one of many lines of evidence that EPA used when considering the rule changes, and EPA utilized the best available peer-reviewed scientific information to qualitatively describe the potential chronic health effects of pesticide use. EPA has tried to be clear in the EA about uncertainties in assigning causality based on epidemiological studies and that the epidemiological results are suggestive, not conclusive, about links between specific pesticides. While many of the cited epidemiological studies have found associations with particular chemicals, they also provide valuable information about the potential impacts of chronic exposure in general. Evidence of elevated risk from a high-quality cohort such as the AHS is a reasonable basis for taking preventative measures.

As a result of an extensive review of the epidemiologic evidence published in the peer-reviewed literature, EPA concludes that there is strong evidence that pesticide exposure contributes to adverse human health outcomes. The environmental epidemiology literature is growing rapidly, however, in terms of both quantity and quality of pesticide epidemiology studies. These illnesses were selected for discussion in the Economic Analysis because they have been associated with pesticide exposures in studies that meet EPA's data quality standards, and due to either the relative strength and plausibility of the hypothesized link, the number of studies available, or the relatively high prevalence of either the health outcome or a particular pesticide exposure. Overall, the totality of reported findings suggests long term health benefits from the rule, but, due to the state of scientific research and measures of chronic exposure at this time, estimates of the quantitative benefits from the final rule are not possible.

<u>Comment</u>. Other commenters suggested that current protections from label requirements are sufficient, and that EPA has not pointed to an increase in exposures or health effects which would justify the rule (1430, 1416, 4541, 1107, 1416).

<u>EPA Response</u>. EPA has concluded that additional protections to workers, handlers and their families are warranted to supplement current label requirements. The changes to WPS will work together to ensure that the label requirements provide their intended protections, to improve pesticide safety. Because of the nature of pesticide exposure, the possible latency of effects, and the underreporting of pesticide incidents, it is difficult to identify reliable trends in pesticide incidents, or to find precise estimates of the benefits of the WPS changes. The available evidence, however, is convincing to EPA that the rule changes will result in benefits from reduced illness sufficient to justify the costs.

<u>Comment</u>. One comment suggested that the evidence for health risks is weak, because the agricultural population is healthier than the general population. The cohort in the Agricultural Health Study has a lower frequency of cancers than the general population. (576).

<u>EPA Response</u>. Although the cohort in the Agricultural Health Study is healthier than the general population by some measures, such as heart disease, there are specific cancers where the cohort has higher incidence of cancer.

<u>Comment.</u> One commenter wrote to say that despite the difficulty in quantifying benefits, the likely increase in health, safety and the environment justify the rule under the precautionary principle (2349).

<u>EPA Response</u>. The FIFRA regulatory scheme of pre-market review of pesticide products is inherently precautionary, however, it is not identical to the Precautionary Principle. Instead, the FIFRA regulatory standard is intended to prevent unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. EPA is confident that the adverse effects targeted by the revisions to the WPS are unreasonable when compared to the costs associated with those revisions to the rule.

<u>Comment</u>. Several commenters wrote to suggest additional literature that reports an association between pesticide exposure and health risks, information on sources of exposure to farmworkers, handlers and their families, and research that shows the importance of occupational health and safety programs for protecting workers (2437, 2250, 4435, 182, 4586, 2376, 2305, 1965, 4464, 99, 2050, 79).

EPA Response. EPA thanks the commenters for this information.

<u>Comment</u>. Several commenters who either provide health care for farmworkers or represent organizations that do, discuss their experience with farmworkers made ill by pesticide exposure, or the difficulties that farmworkers face in receiving health care (2315, 99, 4576, 4401).

<u>EPA Response</u>. Thank you for this information. The WPS changes should reduce the exposure to agricultural pesticides, which will reduce the need for expensive medical care.

<u>Comment</u>. One commenter suggested that the demographic profile of farmworkers in Hawaii is different than on the mainland, and that the risks of exposure based on the experience of mainland agriculture do not reflect risks on Hawaii (4534).

<u>EPA Response</u>. The demographic profile of farmworkers affects some requirements, like providing training in a manner that can be understood, but is not a factor in the risks of pesticide exposure. The basic protective requirements of pesticide labels and the WPS do not depend on the demographics of the worker.

<u>Comment.</u> One commenter was concerned that EPA is primarily concerned with risks to farmworkers, handlers and their families, while ignoring the potential effect on other rural residents such as babies, children, pregnant women, and those who are already ill or disabled, along with those taking medication, which the European Union defines as a "vulnerable group" (1886).

<u>EPA Response</u>. Although the WPS focuses on protecting workers and handlers, some revisions may also reduce the potential for exposure to bystanders, i.e., people not employed by the establishment making a pesticide application provide protection to bystanders. There is mention of bystanders in the introductory material and in Chapter 4 of the Economic Analysis. See Units IX and XVIII.B for an explanation about how the WPS protects bystanders from being sprayed, directly or through drift, and the protections in WPS for people other than workers and handlers.

<u>Comment</u>. One commenter requested information on EPA's estimate of under-reporting of pesticide incidents.

<u>EPA Response</u>. There are few studies available that quantify the extent of underreporting, even though the existence of pesticide incidents that are not reported in surveillance databases is widely

acknowledged. The discussion of the basis for underreporting estimates is provided in Section 4.5.2 of the Economic Analysis.

<u>Comment.</u> One commenter suggested that there is vast under-reporting of pesticide-related illness among farmworkers, partly due to fear of employer retaliation and the absence of a national pesticide incident reporting system. Without reporting and basic protections, farmworkers and their families are at risk for both acute illness and long-term health conditions associated with these exposures and from take-home exposures (4418).

<u>EPA Response</u>. EPA agrees that under-reporting of pesticide incidents is substantial, and the WPS changes are intended to reduce the risks to farmworkers and their families.

<u>Comment.</u> A commenter provided incident data on pesticide exposure and illness from Michigan, citing specific examples that the commenter suggests would have been prevented by the changes to the WPS (87).

<u>EPA Response</u>. Thank you for this information. Many of these incidents are similar to ones that were included in EPA's review of incidents in SENSOR-Pesticides from 2008 to 2011. The additional protections in the WPS should help prevent incidents like many of these, for situations that are within the scope of the WPS.

<u>Comment</u>. Commenters suggested that the number of incidents reported is low, and most are do not result in high severity illnesses. The commenters also said that the number of incidents is small when compared to the amount of pesticides applied nationally, and that most pesticides are applied without incident (4549, 4561).

EPA Response: EPA acknowledges that the vast majority of pesticides are applied without significant adverse effects. However, there are risks from pesticide exposure, and there is evidence that exposures occur among agricultural workers at levels that can cause adverse effects. There are few studies available that quantify the extent of incident underreporting, even though the existence of pesticide incidents that are not reported in surveillance databases is widely acknowledged.

<u>Comment.</u> A commenter reports that there is strong evidence that tracking pesticide illnesses in a longitudinal fashion has probably significantly reduced pesticide risks in a number of settings, over study intervals spanning a decade or more. The commenter encourages EPA to develop an improved database of pesticide illnesses, and encourage state-level databases of pesticide illness similar to California. As part of that database, a definition of "pesticide illness" is necessary, and the commenter recommends the term be defined broadly, to capture known and suspected pesticide illnesses. One commenter further notes that EPA is required under Section 20 of FIFRA to develop a national pesticide incident reporting system (30, 4452).

EPA Response. EPA does maintain a database of reported pesticide incidents, the Incident Data System (IDS). In addition to the IDS and NPIC, EPA looks at a variety of other databases for pesticide incident information, such as those maintained by the American Association of Poison Control Centers, the National Institute for Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (SENSOR) and California's Pesticide Incident Surveillance Program (PISP). Each of these databases has differences in scope, and there is significant overlap, but collectively, they provide a useful perspective on pesticide exposure incidents. Given the availability of these databases, it is not clear that developing another EPA database or requiring all states to develop pesticide surveillance databases would produce information that is so much more reliable as to justify their costs. Requiring employers to track and keep records of all pesticide illnesses on the farm or handler establishment would be at least as expensive, and EPA is concerned that employers would not have the skill and

information to record incidents reliably. More information on reporting pesticide incidents to EPA can be found here: http://www2.epa.gov/pesticide-incidents.

<u>Comment</u>. Commenters suggest that data from the SENSOR website suggests that there is no difference between pesticide incidents for hispanics and non-hispanics, therefore the demographics of the farmworker population does not require rule changes, and that there is no evidence of increasing trends in pesticide incidents (1024).

<u>EPA Response</u>. The demographic profile of farmworkers affects some requirements, like providing training in a manner that can be understood, but is not a factor in the risks of pesticide exposure. The basic protective requirements of pesticide labels and the WPS do not depend on the demographics of the worker.

<u>Comment</u>. A commenter provided some statistics on the numbers of pesticide incidents that occur, both in the US and nationally, and the number that are treated in health care facilities. The large scale manufacture and use of pesticides can lead to many potential incidents (1).

EPA Response. Thank you for this information.

<u>Comment</u>. A commenter suggests that EPA has not been successful in preventing pesticide incidents to date, and that the available data suggest that farmworkers face a much greater risk of pesticide poisoning that other workers, and that the risks of long-term illnesses are substantial (4452).

<u>EPA Response</u>. EPA disagrees that we have not been successful in preventing agricultural pesticide incidents. As discussed in the preamble in Unit IV.B.2, the number of incidents has dropped substantially in the years since WPS was first promulgated. However, we agree that more can be done and these revisions to the WPS are intended to further reduce the number of incidents.

<u>Comment</u>. A commenter notes that EPA is unable to put a value on prevented chronic illnesses from pesticide exposure, and does not believe that estimating the value of prevented illness from the break-even analysis is realistic (425).

<u>EPA Response</u>. EPA agrees that it is very difficult to quantify the extent to which these WPS revisions will reduce chronic illness, but nevertheless, it is reasonable to expect that the revised WPS will reduce chronic illness among agricultural workers and handlers, and thereby make an important contribution to the long-term health of workers, handlers and their families. The break-even analysis acknowledges that exposure and risk information is unavailable to fully quantify the changes in chronic illness from the rule, while providing a way for the public to understand the importance of potential changes in risks from pesticide exposure. More information on the break-even approach can be found in Section 7.5.2 of the EPA Guidelines for Preparing Economic Analyses, available here: http://yosemite.epa.gov/ee/epa/eerm.nsf/vwAN/EE-0568-50.pdf/\$file/EE-0568-50.pdf.

Comment. One commenter recommended an additional review of data from SENSOR-Pesticides, state level incident data, and toxicology data from registrations with respect to specific questions. After completing such a review, EPA will have sufficient data to support the rule changes. The questions included were: How many illnesses were attributable to label violations? How many are attributed to poor training? How many incidents or illness are attributed workers forgetting training in the fourth, third year, or second year after their initial training? How often are these standards enforced? How many violations are reported and for what? Is the EPA registration process not providing enough safety? What percentages are attributed to each type of incident and what proposed rule change would inhibit this type of incident?

<u>EPA Response</u>. EPA has updated the analysis for the final rule using the most recent data from SENSOR-Pesticides. For that task, the information in SENSOR-Pesticides was reviewed, and estimates of reduced incidents from the rule changes include only incidents where the WPS applies, and only

incidents where there was sufficient information for EPA to determine that the incident could have been prevented by the rule changes. The remaining questions, such as the number of incidents attributed to workers forgetting training in specific years, are unanswerable without records of training for incident investigators. Other questions, such as those concerning enforcement actions and recorded violations are unlikely to change EPA's conclusions that changes to the WPS are warranted, which were based on the evaluation of available incident data along with information on the effects of chronic pesticide exposure.

<u>Comment.</u> A commenter believes that the estimates of under-reporting of pesticide incidents are in error and ambiguous. If true, this would negate much of the quantified benefits from the rule (2971).

<u>EPA Response</u>. EPA benefit estimates from prevented acute pesticide incidents are based on the best available data collected by pesticide surveillance databases. There are few studies available that quantify the extent of underreporting, even though the existence of pesticide incidents that are not reported in surveillance databases is widely acknowledged. The discussion of the basis for underreporting estimates is provided in Section 4.5.2 of the Economic Analysis.

<u>Comment</u>. In the preamble to the proposed rule, EPA states that "changes to the current WPS requirements are expected to lead to an overall reduction in incidents of unsafe pesticide exposure and to improve the occupational health of the nation's agricultural workers and pesticide handlers." Yet a full reading of the rule shows that in the overwhelming majority of instances, the agency can identify no discernible or identifiable benefits that will result from the burdens and regulatory requirements it proposes to impose on employers.

<u>EPA Response</u>. There are many changes to the WPS, and the changes work together to increase safety. For example the better communication of hazards works together with better training to ensure that farmworkers and handlers know better how to protect themselves and their families. The changes also work together with pesticide labels to ensure that pesticides can be used safely. Because changes are meant to work together, and because it is impractical to test each of the element of the WPS is isolation, EPA cannot quantify the benefits of individual proposals. Because of the nature of pesticide exposure, the possible latency of effects, and the underreporting of pesticide incidents, it is difficult to find precise estimates of the benefits of the WPS changes. The available evidence, however, is convincing to EPA that the rule changes will result in benefits sufficient to justify the costs.

Comment. This shortcoming is nowhere more glaring than in the agency's failure to use relevant, recent information from the Sentinel Event Notification System for Occupational Risks (SENSOR) Pesticide Program. SENSOR currently contains information from eleven states and has data for pesticide exposures for the years 1998-2006, during which time approximately 5,200 cases of individuals with acute occupational pesticide-related illness were identified.

We have incorporated below three tables derived from the SENSOR website. These three tables break out instances of acute occupational pesticide-related illness estimates by severity of exposure for three categories: overall (Table 1); for Hispanics (Table 2); and for non-Hispanics (Table 3). What is remarkable about all of them is the consistency they show. Trend lines do not indicate a worsening of pesticide exposures, either in numbers or severity. Perhaps more importantly, they appear to show no evidence between the types and severity of exposures between Hispanics (the predominant demographic for agricultural workers) and others. This runs counter to the agency's assumption that the demographics of this population calls for stricter, tighter requirements on agricultural employers.

<u>EPA Response</u>. The demographic profile of farmworkers affects some requirements, like providing training in a manner that can be understood, but is not a factor in the risks of pesticide

exposure. The basic protective requirements of pesticide labels and the WPS do not depend on the demographics of the worker. EPA notes that the data cited by the commenter includes exposure incidents to all kinds of pesticides, although the WPS is limited to agricultural pesticides.

<u>Comment</u>. Assuming reductions in chronic illnesses caused by pesticide exposures resulting from labelled directions implies that EPA's risk assessment and regulatory decision making processes are flawed. This is not the case. The benefits – i.e. the reductions in acute and chronic disease that EPA proposes, are inappropriately and unscientifically determined.

<u>EPA Response</u>. EPA produces robust assessments of the potential occupational risks to agricultural workers, considering the totality of known or predicted pesticide toxicities in the human population (based upon animal studies); the type, timing and duration of exposure (based upon registrant supported label uses and application practices); and the relationship between hazard and exposure, based upon the nature of the quantitative relationship and science policy (uncertainty factors). As a result of our assessments, EPA is able to adequately determine that anticipated pesticide exposure in the occupational population is acceptable when label practices are followed, i.e., anticipated exposure does not exceed that which would result in an adverse health effect under label prescribed conditions. However, EPA neither states that pesticide exposure anticipated among agricultural workers is absent (EPA aims to prevent unreasonable risk)), nor does the Agency predict risk to human health in hypothesized instances in which the label directions are not followed. Despite the efforts of pesticide registrants, growers and other members of the agricultural community to ensure label conditions are followed in practice, given the magnitude and scope of pesticide use in the U.S., some intentional or unintentional misuse of pesticides may be inevitable.

<u>Comment</u>. EPA admits that quantifying disease reduction is impossible. Their method to determine benefit makes it impossible to determine whether or not the revisions have been successful, and thereby determine if the cost was warranted. By using chronic disease as a metric for success, EPA has created an ever moving target and an endless requirement for revisions to the WPS without measurable performance metrics.

<u>EPA Response</u>. EPA acknowledges its current inability to determine the number of illnesses that will be reduced by changes to the WPS. For the analysis of the changes to the WPS, EPA follows guidelines from The Office of Management and Budget¹ which suggest using a threshold or "breakeven" analysis when quantification of monetary benefits is not possible.

<u>Comment</u>. Again, EPA authors have left out important data on trends, data which demonstrate (i) ongoing reductions in acute poisoning, (ii) that agriculture workers are actually healthier relative than their non-farm worker peers, and (iii) which demonstrate significant improvements in farm worker demographics since 1992.

<u>EPA Response</u>. EPA's analysis for the final rule has been updated with the most recent SENSOR data. EPA's evaluation of the available incident data and information on the effects of chronic pesticide exposure led the Agency to conclude the changes were warranted. Much of the information about the health of the farm population is from the Agricultural Health Study. While the Agricultural Health Study cohort of certified pesticide applicators and their families have lower rates of many diseases, such as heart disease, than the general population, the cohort has higher risk than the general public of other chronic diseases. The primary purpose of the rule, however, is to protect farmworkers, pesticide handlers and

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¹ OMB Circular A-4: https://www.whitehouse.gov/omb/circulars a004 a-4/

their families. EPA has little information about how the health of current and former agricultural workers compares to the general population or farm owners.

<u>Comment.</u> It is unclear how the recommended training and record keeping will result in a quantifiable and measurable reduction in acute incidents or chronic illness, and in particular how these reductions – on which the cost of these improvements are based – can or will be measured. Without this, EPA will be unable to make a future assessment as to whether these proposed revisions, if implemented, have been effective and the money well spent.

<u>EPA Response</u>. There are many changes to the WPS, and the changes work together to increase safety. For example the better communication of hazards works together with better training to ensure that farmworkers and handlers know better how to protect themselves and their families. The changes also work together with pesticide labels to ensure that pesticides can be used safely. For these reasons, the benefits of individual proposals could not be estimated. Because of the nature of pesticide exposure, the possible latency of effects, and the underreporting of pesticide incidents, it is difficult to find precise estimates of the benefits of the WPS changes. The available evidence, however, is convincing to EPA that the rule changes will produce benefits sufficient to justify the costs.

<u>Comment</u>. The costs of additional training should reflect reductions in acute illnesses only, and reference to reducing chronic illness be removed as it is not supported by the scientific evidence, or by the EPA risk assessments that have been conducted on all the pesticide products currently on the market.

EPA Response. Despite continual efforts to improve safety, risks to farmworkers, handlers and their families remain. Epidemiology studies of chronic health risks, such as the Agricultural Health Study are one of many lines of evidence that EPA used when considering the rule changes. EPA utilized the best available peer-reviewed scientific information to qualitatively describe the potential chronic health effects of pesticide use. EPA has tried to be clear in the EA about uncertainties in assigning causality based on epidemiological studies and that the epidemiological results are suggestive, not conclusive, about links between specific pesticides. While many of the cited epidemiological studies have found associations with particular chemicals, they also provide valuable information about the potential impacts of chronic exposure in general. Information from such a high-quality cohort such as the AHS should not be dismissed.

<u>Comment</u>. CropLife America (CLA) rejects the implicit statement that the EPA has failed in its mandate to protect farm workers. CLA instead contends that a thorough and accurate evaluation of the alleged unreasonable adverse effects, through analysis of morbidity and mortality data, discredits the Agency's underlying assumption that current exposures under the WPS present unacceptable acute and chronic health effects. Analysis of the illness data for agricultural workers suggest that the current WPS and other changes in pesticide practices since 1992 have lowered the level of morbidity and mortality, such that the proposed revisions, with their additional imposed burdens and costs to American agricultural, are unlikely to yield additional reductions. CLA contends that a "modernization" of the existing WPS and associated training to reflect the reality that exists today is not sufficient to continue this downward trend in morbidity and mortality associated with acute pesticide exposures.

<u>EPA Response</u>. EPA's pesticide registration, reregistration, and registration review processes assess the specific risks associated with the particular uses of individual pesticides to ensure that people and the environment do not suffer unreasonable adverse effects. EPA implements any risk reduction and mitigation measures that result from the pesticide reregistration and registration review programs

through individual pesticide product labeling. In doing so, EPA assumes that the labeling is followed. Despite improvements in labels, however, incidents continue to occur and these incidents can be serious. Moreover, the fact that avoidable incidents occur strongly suggests that applicators do not always follow use directions precisely. Given that reported incidents are (a) underreported, and (b) likely only be reported where there is an immediately notable adverse effect, it is reasonable to infer that workers and handlers experience repeated exposures that do not, by themselves, rise to the level of an identifiable incident. EPA has reviewed epidemiological studies, which are a type of retrospective analysis, that focus on pesticide applicators to better understand the potential impacts associated with such chronic exposure. While many of the cited epidemiological studies have sought to establish associations with particular chemicals, it is also significant that they indicate elevated risks of certain chronic illnesses are associated with exposure to pesticides in general. This may be the result of cumulative or synergistic effects of different pesticides. Although EPA could require pesticide registrants to generate studies on the vast number of pesticide combinations and exposure scenarios, the costs of such studies appears prohibitive.

In the analysis for the Final Rule, EPA used the most recent available incident data to estimate the reduction in illness from the rule, and concluded that the changes in the rule were warranted. EPA can regulate prescribed pesticide use (i.e., enforce the pesticide label; the label is the law), however, EPA cannot regulate human exposure (which reflects unintentional accidents, human error, off-label or misuse) to pesticides. The break-even analysis demonstrates that avoidance of a small number of possible cases of pesticide induced chronic disease outweighs the costs imposed by these commonsense enhancements to the WPS. EPA believes it is good public health practice to amend the WPS for these reasons.

Comment. However, we question EPA's assumption that only 25% of acute poisonings are reported, and that those which are under reported are sufficiently severe to incur a cost. EPA's stated reason for under reporting is given as "many symptoms of pesticide poisoning, such as fatigue, nausea, dizziness and diarrhea may be confused with other illnesses and may not be reported by the workers as related to their occupational exposure." But is this really under reporting, or is this because these symptoms are, in fact, caused by things other than pesticide exposure? Or is the under reporting a reflection of the symptoms not being severe enough to lead a worker to seek treatment, or prevent him from going to work? Without more information on the reasons why 75% of pesticide related illness goes unreported, it is not reasonable to assume – as the EPA does - lost wages and medical costs. In other words, increasing the cost burden associated with acute poisonings, based on an assumption of under reporting alone, is illogical and untenable.

EPA Response. EPA benefit estimates from prevented acute pesticide incidents are based on the best available data collected by pesticide surveillance databases. There are few studies available that quantify the extent of underreporting, even though the existence of pesticide incidents that are not reported in surveillance databases is widely acknowledged. The discussion of the basis for underreporting estimates is provided in Section 4.5.2 of the Economic Analysis. This section details reasons why experts in the field consider occupational pesticide incidents, especially agricultural pesticide incidents to be underreported. A number of steps are necessary before a pesticide incident is recorded; a breakdown in any one of which would cause an unreported pesticide illness. These include (1) workers must perceive that they have treatable symptoms; (2) workers must seek medical attention; (3) the physician must diagnose the symptoms as being pesticide related; and (4) the physician or the injured person must report the incident to the correct recordkeeping system, and the incident must be

recorded as pesticide related. There is another step whereby exposure incidents are not reported to the SENSOR-Pesticides database used in this analysis. If a record does not meet the criteria for inclusion in a surveillance database, it means that an exposure will not be recorded, reported and available for review. This fifth step can exclude many potential cases that would be relevant to evaluating the changes to the WPS. The information presented in Section 4.5.2 of the Economic Analysis of the final rule has lead EPA to conclude that the underreporting estimates are reasonable.

<u>Comment.</u> Information from a number of sources could assist in determining (i) the real magnitude of the problem to be addressed and (ii) the most appropriate training requirements in order to address it. Sources include California PISP data, NPDS, NIOSH SENSOR data and often provide detailed accounts of the circumstances under which the incidents took place, thus allowing for better tailoring of WPS training needs. EPA should examine the nature of pesticide related incidents and illnesses and their causes in greater detail before deciding possible solutions to put forward. EPA should reference its own data on real life exposures and reference doses as part of its analysis of the WPS.

<u>EPA Response</u>. For the analysis of the final rule EPA used the most recent available data from SENSOR-Pesticides, and was careful to only include incidents that could be prevented by the changes to the WPS. EPA has relied on the best currently available information on pesticide incidents, and considers it, in combination with the epidemiology literature on the effects of pesticide exposure to be sufficient justification to support the WPS revisions.

Comment. The break even analysis suggests that the benefits are limited to very few cases and reduced cancer and illness rates will be too small to be measured. This also means it will not be possible to judge whether the revised WPS have worked or not. The causal evidence between exposure to pesticides and the chronic diseases cited has not been demonstrated. In light of the extensive controlled and laboratory studies available for individual pesticides the Agency should not be including cancer rates in their benefit analyses, even for illustrative purposes. Of great concern is a tacit admission that the Office of Pesticide Programs has failed in its primary mission under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to only register a pesticide the Agency determines that when used in accordance with the label it will not generally cause unreasonable adverse effects to handlers and workers. Specifically CLA supports efforts of the WPS to comply with the label.

<u>EPA Response</u>. EPA does not use the breakeven analysis to estimate the number of incidents of chronic illness that will be reduced because of the changes to the WPS. The breakeven analysis was used to show that only a very small reduction in the number of chronic illnesses would equal the cost of the WPS.

EPA's Economic Analysis presented information from epidemiology studies on the potential for adverse chronic health effects from pesticide exposure. EPA relied on these studies due to the relative strength of the hypothesis (plausibility), and the quality and quantity of the epidemiological research in the human population, as well as other scientific information. These data (peer-reviewed, published epidemiology studies) were reviewed by EPA in accordance with our stated data quality practices, and reflected in the qualitative conclusions of the chronic health benefits section.

EPA understands the limitations with epidemiological literature. EPA concurs that it would be imprudent to characterize any of the statistical associations referenced in the chronic benefits section of the EPA economic analysis of the WPS rulemaking between a specific pesticide exposure and a specific chronic disease outcome as causal in nature. For this reason, EPA repeatedly stated in the document that it is premature to make this conclusion for any specific pesticide-disease association. But the

absence of a pesticide-specific conclusion does not diminish the significance of the association between specific chronic health problems and elevated exposure to pesticides generally.

EPA produces robust chemical-specific assessments of the potential occupational risks to agricultural workers, considering the totality of known or predicted pesticide toxicities in the human population (based upon animal studies); the type, timing and duration of exposure (based upon registrant supported label uses and application practices); and the relationship between hazard and exposure, based upon the nature of the quantitative relationship and science policy (uncertainty factors). As a result of our assessments, EPA is able to adequately determine that anticipated pesticide exposure in the occupational population is acceptable when label practices are followed, i.e., anticipated exposure does not exceed that which would result in an adverse health effect under label prescribed conditions. However, registration does not signify the absence of pesticide exposure or pesticide risk among agricultural workers (EPA aims to prevent unreasonable risk), and the Agency does not routinely predict the full extent of the risk to human health in hypothesized instances in which the label directions are not followed. If all users scrupulously followed label requirements and the best use practices regarding training, notification, and hygiene at all times, acute poisoning incidents among occupationally exposed persons should be low and would only include accidents. However, acute poisoning surveillance databases suggest otherwise, indicating that further improvements are possible.

Further, while difficult to capture in a pesticide surveillance database, it is possible that an accumulation of acute exposures over time could lead to long-term health effects that are outside the scope of the studies EPA requires in support of registration. EPA considers the results of both acute poisoning surveillance data and chronic disease epidemiology studies to offer valuable insight into the actual risk in "real world" circumstances. EPA does consider the epidemiological findings presented in the WPS EA to be an important part of the body of evidence that supports the suite of proposed regulatory amendments that, taken together, will provide protections that will lead to an overall reduction in the burden of disease among the exposed population.

This conclusion is qualitatively supported by evaluating the studies in which use of any pesticide or any member of a large group of pesticides such as organophosphates or pyrethroids have been positively associated in the literature with chronic disease. Furthermore, review articles and/or meta-analytic results evaluating all pesticides have also observed significant relationships, potentially suggesting a generalized role for pesticide exposure in the agricultural environment as a risk factor for disease.

Comment. CLA proposes that costs associated with revisions to the WPS can only be meaningfully balanced by reductions in the incidence of acute poisonings and that reference to chronic disease should be excluded from the cost estimates. The causal role of pesticides in chronic disease is unfounded and reductions in chronic disease due to reductions in chronic exposure are therefore unlikely and un-measurable. Referencing chronic disease in the preamble becomes unnecessary and should be removed, or at least rebalanced by (i) using a scientific literature review that includes toxicological data as well as epidemiology data, and (ii) which follows recommended best practice including the EPA Office of Pesticide Programs recommendations and guidelines such as their 2010 document "Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment", http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2009-0851, or the Weight of Evidence process EPA follows when incorporating other scientifically relevant information into a risk assessment.

<u>EPA Response</u>. EPA disagrees with the commenter's characterizations of the evidence of chronic illnesses associated with general pesticide exposure, and disagrees with the contention that such

7597 evidence may not be used to support regulatory action. In the economic analysis and preamble of the 7598 proposed rule, EPA explained the possible risks from chronic pesticide exposure, and discussed the peer-7599 reviewed, scientific literature exploring possible associations between chronic pesticide exposure and 7600 illness. In this process, EPA was careful to identify the relevant studies, and describe the possible 7601 associations in line with EPA's Principles of Scientific Integrity (http://www.epa.gov/osa/pdfs/epa-7602 principles-of-scientific-integrity.pdf). Much effort was expended to ensure that the cited studies were presented in such a way that the public could clearly understand any uncertainties that necessarily 7603 7604 remain in such a field. These works were all from peer-reviewed journals, and meet EPA standards for 7605 peer reviewed work (http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2012.pdf). The 7606 WPS analysis was careful to note the difficulty of moving from epidemiological results indicating an 7607 association to the determination of a causal link between specific pesticide exposures and chronic 7608 health effects. Only a subset of possible associations in the literature were included. Several other 7609 associations have been measured in the literature, and the ones selected for discussion in the WPS 7610 analysis were chosen due to either the relative strength and plausibility of the hypothesized link, the 7611 number of studies available, or the relatively high prevalence of either the health outcome or a 7612 particular pesticide exposure. Also important to EPA is the role of describing potential risks in a way 7613 that can be understood by both scientists and the general public while being clear about scientific 7614 uncertainty. To that end, OPP follows the standards in the EPA Science Policy Council Risk 7615 Characterization Handbook (http://www.epa.gov/spc/pdfs/rchandbk.pdf), which provides guidance on 7616 how to achieve the goals of "transparency, clarity, consistency, and reasonableness" when conveying 7617 the risk assessors' judgement to the public. For this purpose, the Agency also follows the EPA and OMB 7618 data quality guidelines. These include the EPA Office of Environmental Information Guidelines for 7619 Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by 7620 the Environmental Protection Agency: 7621 (http://www.epa.gov/quality/informationguidelines/documents/EPA InfoQualityGuidelines.pdf) as well 7622 as the Office of Management and Budget Guidelines for ensuring and maximizing the quality, objectivity,

(http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf) as well as the Office of Management and Budget Guidelines for ensuring and maximizing the quality, objectivity utility, and integrity of information disseminated by federal agencies (http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf).

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Whether evaluating data, analyzing EPA policy, or presenting results to the public, peer review plays an important role at OPP, where we follow the guidance in the EPA Science Policy Council Peer Review Handbook (http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf), and abide by EPA's Principles of Scientific Integrity (http://www.epa.gov/osa/pdfs/epa-principles-of-scientific-integrity.pdf).

<u>Comment</u>. However, the preamble narrative implying an estimated number of chronic illnesses are linked to various pesticide exposures is not supported by scientific data and is in conflict with the Agency's registration and reregistration review programs.

<u>EPA Response</u>. EPA has tried to be clear in the Economic Analysis and preambles to the proposed and final rule about uncertainties in assigning causality based on epidemiological studies and that the epidemiological results are suggestive, not conclusive, about links between specific pesticides. While many of the cited epidemiological studies have found associations with particular chemicals, they also provide valuable information about the potential impacts of chronic exposure in general. Evidence of elevated risk from a high-quality cohort such as the AHS is a reasonable basis for taking preventative measures.

As a result of an extensive review of the epidemiologic evidence published in the peer-reviewed literature, EPA concludes that there is strong evidence that pesticide exposure contributes to adverse

human health outcomes. The environmental epidemiology literature is growing rapidly, however, in terms of both quantity and quality of pesticide epidemiology studies. These illnesses were selected for discussion in the Economic Analysis because they have been associated with pesticide exposures in studies that meet EPA's data quality standards, and due to either the relative strength and plausibility of the hypothesized link, the number of studies available, or the relatively high prevalence of either the health outcome or a particular pesticide exposure. Overall, the totality of reported findings suggests long term health benefits from the rule, but, due to the state of scientific research and measures of chronic exposure at this time, estimates of the quantitative benefits from the final rule are not possible.

Comment. EPA has embraced the arguments and objectives of farmworker organizations, while apparently overlooking the input from actual state co-regulators; based many arguments on outdated worker demographics; and made unfounded assumptions regarding worker exposures and chronic illnesses, without supporting scientific evidence. Had the Agency cited current literature, it would have acknowledged significantly improved farmworker demographics and safety since 1992; a steep and ongoing reduction in incidents of acute poisoning; and a lack of evidence of elevated levels of chronic illnesses among farmworkers. EPA cites a reduction in such illnesses and associated risks under the estimated benefits to the Proposed Rule, but admits it is "not able to quantify the benefits expected to accrue from the proposed WPS changes that would reduce chronic exposure to pesticides." The PPC is very concerned that the assumptions and rhetoric of the Preamble discredit the rigor of EPA's pesticide registration and registration review processes; overlooks the many advances in new pesticide products and application technologies made since 1992; and dismisses the extensive worker-protection stewardship programs of states, registrants, professional applicators and agricultural producers.

<u>EPA Response</u>. For the final rule, EPA has updated the data on pesticide incidents, and updated the information on farmworker demographics.

Despite continual EPA efforts to improve safety, risks to farmworkers, handlers and their families remain. Studies of pesticide risks, such as epidemiology studies, such as the Agricultural Health Study (AHS) are one of many lines of evidence that EPA used when considering the rule changes, and EPA utilized the best available peer-reviewed scientific information to qualitatively describe the potential chronic health effects of pesticide use. EPA has tried to be clear in the EA about uncertainties in assigning causality based on epidemiological studies and that the epidemiological results are suggestive, not conclusive, about links between specific pesticides. While many of the cited epidemiological studies have found associations with particular chemicals, they also provide valuable information about the potential impacts of chronic exposure in general. Information from such a high-quality cohort such as the AHS should not be dismissed.

As a result of an extensive review of the epidemiologic evidence published in the peer-reviewed literature, EPA concludes that there is strong evidence that pesticide exposure contributes to adverse human health outcomes. The environmental epidemiology literature is growing rapidly, however, in terms of both quantity and quality of pesticide epidemiology studies. These illnesses were selected for discussion in the Economic Analysis because they have been associated with pesticide exposures in studies that meet EPA's data quality standards, and due to either the relative strength and plausibility of the hypothesized link, the number of studies available, or the relatively high prevalence of either the health outcome or a particular pesticide exposure. Overall, the totality of reported findings suggests long term health benefits from the rule, but, due to the state of scientific research and measures of chronic exposure at this time, estimates of the quantitative benefits from the final rule are not possible.

<u>Comment</u>. A business advocacy organization asserted that EPA's statements about the WPS reducing chronic diseases, and about pesticide exposure being associated with chronic disease, are

inaccurate, misleading, unreliable, biased, and not based on reproducible studies. This commenter asserted that the studies and data supporting the break-even analysis in the EA, and therefore the proposed rule, violate EPA's IQA Guidelines and EPA's other data requirements for pesticides.

The commenter argues that there is no scientifically supportable correlation between general pesticide exposure, as currently regulated, and chronic disease, and that any chronic disease concerns are adequately addressed during pesticide registrations. Consequently, the commenter contends that there is no rational basis for counting reduction of chronic disease as a benefit of the WPS, and thus no rational basis for the Agency's Economic Analysis.

The commenter also argues that EPA's assumption of an association between chronic human disease and general pesticide exposure is irreconcilable with EPA's conclusions during FIFRA registrations that individual pesticides do not pose any significant risk of human chronic disease. The commenter argues that any chronic disease concerns are adequately addressed during pesticide registrations, and that the Economic Analysis therefore ignores or contradicts EPA's previous determinations in individual pesticide registration decisions.

The commenter further argues that the Economic Analysis is also inconsistent with OMB guidance because it does not include a Monte Carlo Analysis of Uncertainty, as required by OMB Circular A-4.

<u>EPA Response</u>. The commenter's view of the Information Quality Act (IQA) is mistaken. EPA has fully adhered to the IQA and to both OMB's government-wide guidance and EPA's own information quality guidelines (IQGs).

The proposed and final WPS are each an ordinary exercise of the Administrator's rulemaking authority pursuant to FIFRA section 25(a), typical of similar exercises of authority. In exercising that authority here, the Agency reasonably relied on reliable, objective evidence, including the best available science, consistent with Executive Order 13563. The thorough consideration provided by the public comment process serves the purposes of the Guidelines, by providing an opportunity for correction of any information that does not comply with the Guidelines. Thus EPA's actions in regard to the WPS revision are fully in accord with both the spirit and the letter of the IQA.

EPA disagrees with the commenter's contention that evidence of the association between general pesticide exposure and chronic health risks does not meet adequate standards of quality required by the IQGs, and as a consequence the Cost-Benefit Analysis also fails to meet the IQGs. To the contrary, the evidence supporting this action includes reliable, objective, peer-reviewed studies showing well-documented associations between pesticide exposure and certain cancer and non-cancer chronic health effects.

Studies of pesticide risks, including epidemiology studies such as the Agricultural Health Study, are one of many lines of evidence that EPA used when considering the rule changes. EPA presented information from epidemiology studies on the potential for adverse chronic health effects from pesticide exposure. EPA utilized the best available peer-reviewed scientific information to qualitatively describe the potential chronic health effects of pesticide use.

In this process, EPA was careful to identify the relevant studies, and describe the possible associations in line with EPA's Principles of Scientific Integrity (http://www.epa.gov/osa/pdfs/epa-principles-of-scientific-integrity.pdf). Much effort was expended to ensure that the cited studies were presented in such a way that the public can clearly understand and evaluate any uncertainties that necessarily remain. The cited literature were all from peer-reviewed journals, and meet EPA standards for peer reviewed work (http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2012.pdf). The WPS analysis was careful to note the difficulty of moving from epidemiological results indicating an

association to the determination of a causal link between specific pesticide exposures and chronic health effects. Only a subset of possible associations in the literature were included.

These studies were identified due to the relative strength of the hypothesis (plausibility), and the quality and quantity of the epidemiological research in the human population, as well as other scientific information. These data (the peer-reviewed, published epidemiology studies) were reviewed by EPA in accordance with our stated data quality practices, and reflected in the qualitative conclusions of the chronic health benefits section. The illnesses were selected for discussion in the Economic Analysis because they have been associated with pesticide exposures in studies that meet EPA's data quality standards, and due to either the relative strength and plausibility of the hypothesized association, the number of studies available, or the relatively high prevalence of either the health outcome or a particular pesticide exposure. Overall, the totality of reported findings suggests long term health benefits from the rule, but, due to the state of scientific research and measures of chronic exposure at this time, estimates of the quantitative benefits from the final rule are not possible.

EPA understands the limitations with epidemiological literature and does not characterize the statistical association in referenced studies as causal in nature. This conclusion is qualitatively supported by evaluating the studies in which use of "any pesticide" or "any member of a large group of pesticides such as organophosphate or pyrethroid" have been positively associated in the literature with chronic disease. Furthermore, review articles and/or meta-analytic results evaluating "all pesticides" have also observed significant relationships, potentially suggesting a generalized role for pesticide exposure in the agricultural environment as a risk factor for disease.

EPA has tried to be clear in the EA about uncertainties in assigning causality based on epidemiological studies and that the epidemiological results are suggestive, not conclusive, about associations between disease and specific pesticides. The environmental epidemiology literature is growing rapidly, however, in terms of both quantity and quality of pesticide epidemiology studies. Also important to EPA is the role of describing potential risks in a way that can be understood by both scientists and the general public while being clear about scientific uncertainty. To that end, OPP follows the standards in the EPA Science Policy Council Risk Characterization Handbook (http://www.epa.gov/spc/pdfs/rchandbk.pdf) which provides guidance on how to achieve the goals of "transparency, clarity, consistency, and reasonableness" when conveying the risk assessors' judgement to the public. For this purpose, the Agency also follows the EPA and OMB data quality guidelines. These include the EPA Office of Environmental Information Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency:

(http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf) as well as the Office of Management and Budget Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies (http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf).

EPA disagrees with the commenter's contention that any chronic disease concerns are irreconcilable with the registrations of the individual pesticides and are adequately addressed during pesticide registrations. First, EPA requires applicants for registration to submit a wide range of data to support the registration, typically including several types of chronic toxicity studies. While the studies EPA does require generally provide a sufficient basis for the Agency to draw reasonable conclusions about the likelihood of the pesticide causing chronic adverse effects, they are not sufficient to rule out the possibility that the pesticide may contribute to chronic effects under certain conditions. Second, EPA does not ordinarily require registrants to test for chronic effects resulting from simultaneous or

sequential exposure to multiple pesticides, with other environmental stressors that may be present in agricultural situations, or with genetically susceptible sub-populations. Relatively little is known about the cumulative or synergistic effects of different pesticides, but such effects may be a factor in the elevated incidence of certain chronic illnesses observed in epidemiology studies of farm populations, like the Agricultural Health Study. In most cases, EPA's registration decisions are not designed to protect agricultural workers against cumulative or synergistic effects of different pesticides unless they have a common mechanism of action. Thus, the WPS provisions work in concert with the individual labels to generally reduce and mitigate multiple pesticide exposures. Third, the fact that a pesticide is registered does not mean that it poses no chronic risk when used according to the label. The FIFRA registration criteria do not set a zero risk standard; instead, FIFRA only requires that a pesticide not generally cause unreasonable adverse effects, taking into account the economic, social, and environmental costs and benefits of its use. As a result, it is to be expected that registered pesticides will cause some measure of adverse effects including as chronic illnesses. These adverse effects would be greater in both frequency and severity without the general workplace practices, precautions, and hygienic measures mandated by the WPS.

EPA disagrees with the commenter's contention that Circular A-4 requires a Monte Carlo analysis. EPA notes that the annual costs associated with the WPS revisions are well below those for which Circular A-4 requires a formal quantitative analysis of uncertainty: "For rules that exceed the \$1 billion annual benefits or costs, a formal quantitative analysis of uncertainty is required. For rules with annual benefits or costs in the range from \$100 million to \$1 billion, agencies should seek to match the more rigor of their approach with the magnitude of a rule's consequences." OMB Circular A-4, p. 41. The WPS EA was reasonable and appropriately rigorous for the magnitude of the rule's consequences. In any case, a Monte Carlo simulation would not be an appropriate tool in this situation. EPA acknowledges that there are no estimates of reduction in exposure for the multitude of potential chemical combinations, nor estimates of a dose-response curve between general pesticide exposure and incidence of various chronic disease. The break-even analysis itself is a tool for understanding the level of uncertainty by estimating the minimum number of cases of chronic illness that must be avoided to equal the cost of the rule.

XXI. References

The following is a listing of the documents that are specifically referenced in this document.

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- 2. EPA. Pesticides; Agricultural Worker Protection Standard Revisions; Proposed Rule. **Federal Register** (79 FR 15444, March 19, 2014) (FRL-9395-8).
- 3. EPA. Final Report: *Small Business Advocacy Review Panel on EPA Planned Revisions to Two Related Rules: Worker Protection Standard for Agricultural Pesticides (RIN 2070-AJ22); and Certification of Pesticide Applicators (RIN 2070-AJ20).* November 3, 2008.
 - 4. EPA. Response to Comments on Proposed Changes to the Worker Protection Standard. 2015.
- 5. U.S. Senate. S. Rep. No. 92-883 (Part II), 92nd Congress, 2nd Session at 43-46 (1972). U.S. Code Congressional and Administrative News 1972, p. 4063.
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- 7. USDA Economic Research Service. Kandel, W. *Profile of Hired Farmworkers, A 2008 Update. Economic Research Report No. 60. U.S. Department of Agriculture. Economic Research Service.* 2008.
 - 8. EPA. Worker Protection Standard: A Summary of the Public's Comments and the Agency's

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